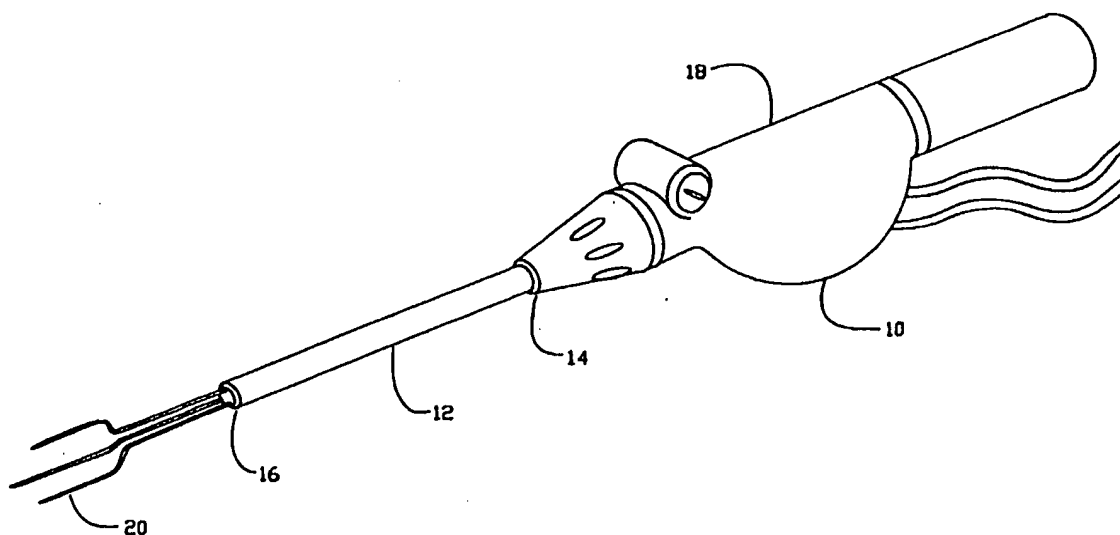


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b>  <b>A61B 17/39</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 98/35619</b>  <b>(43) International Publication Date:</b> 20 August 1998 (20.08.98)
<b>(21) International Application Number:</b> PCT/US97/22477  <b>(22) International Filing Date:</b> 9 December 1997 (09.12.97)  <b>(30) Priority Data:</b> 08/801,739 14 February 1997 (14.02.97) US  <b>(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application</b> US 08/801,739 (CIP) Filed on 14 February 1997 (14.02.97)  <b>(71) Applicant (for all designated States except US):</b> RITA MEDICAL SYSTEMS, INC. [US/US]; 967 North Shoreline Boulevard, Mountain View, CA 94043 (US).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> EDWARDS, Stuart, D. [US/US]; 658 Westridge Drive, Portola Valley, CA 94028 (US). LAX, Ronald, G. [US/US]; 2740 S.W. Martindown Boulevard #300, Palm City, FL 34990 (US). SHARKEY, Hugh [US/US]; 935 Corriente Pointe Drive, Redwood Shores, CA 94065 (US).		<b>(74) Agent:</b> DAVIS, Paul; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).  <b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>

**(54) Title:** MULTIPLE ELECTRODE ABLATION APPARATUS**(57) Abstract**

A tissue ablation apparatus includes a delivery catheter with distal and proximal ends. A handle is attached to the proximal end of the delivery catheter. At least partially positioned in the delivery catheter is an electrode deployment device. The electrode deployment device includes a plurality of retractable electrodes. Each electrode has a non-deployed state when it is positioned in the delivery catheter. Additionally, each electrode has a distended deployed state when it is advanced out of the delivery catheter distal end. The deployed electrodes define an ablation volume. Each deployed electrode has a first section with a first radius of curvature. The first section is located near the distal end of the delivery catheter. A second section of the deployed electrode extends beyond the first section, and has a second radius of curvature, or a substantially linear geometry.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## MULTIPLE ELECTRODE ABLATION APPARATUS

5

### CONTINUING APPLICATION DATA

This application is a continuation-in-part of U.S. Serial No. 08/515,379 filed August 15, 1995 entitled MULTIPLE ELECTRODE ABLATION APPARATUS, which is a continuation-in-part of U.S. Patent No. 5,536,267, issued July 7, 1996 entitled MULTIPLE ELECTRODE ABLATION APPARATUS, which is a continuation-in-part of U.S. Patent No. 5,458,597, issued October 17, 1995, entitled DEVICE FOR TREATING CANCER AND NON-MALIGNANT TUMORS AND METHODS.

10

### BACKGROUND OF THE INVENTION

15

#### Field of the Invention

This invention relates generally to an apparatus for the treatment and ablation of body masses, such as tumors, and more particularly, to a retractable multiple needle electrode apparatus that surrounds an exterior of a tumor with a plurality of needle electrodes and defines an ablative volume.

20

#### Description of Related Art

25

Current open procedures for treatment of tumors are extremely disruptive and cause a great deal of damage to healthy tissue. During the surgical procedure, the physician must exercise care in not cutting the tumor in a manor that creates seeding of the tumor, resulting in metastasis. In recent years development of products has been directed with an emphasis on minimizing the traumatic nature of traditional surgical procedures.

30

There has been a relatively significant amount of activity in the area of hyperthermia as a tool for treatment of tumors. It is known that elevating the temperature of tumors is helpful in the treatment and management of cancerous

tissues. The mechanisms of selective cancer cell eradication by hyperthermia are not completely understood. However, four cellular effects of hyperthermia on cancerous tissue have been proposed, (i) changes in cell or nuclear membrane permeability or fluidity, (ii) cytoplasmic lysosomal disintegration, causing release of digestive enzymes, (iii) protein thermal damage affecting cell respiration and the synthesis of DNA or RNA and (iv) potential excitation of immunologic systems. Treatment methods for applying heat to tumors include the use of direct contact radio-frequency (RF) applicators, microwave radiation, inductively coupled RF fields, ultrasound, and a variety of simple thermal conduction techniques.

Among the problems associated with all of these procedures is the requirement that highly localized heat be produced at depths of several centimeters beneath the surface of the body. Certain techniques have been developed with microwave radiation and ultrasound to focus energy at various desired depths. RF applications may be used at depth during surgery. However, the extent of localization is generally poor, with the result that healthy tissue may be harmed.

Induction heating gives rise to poor localization of the incident energy as well. Although induction heating may be achieved by placing an antenna on the surface of the body, superficial eddy currents are generated in the immediate vicinity of the antenna. When it is driven using RF current unwanted surface heating occurs diminishing heating to the underlying tissue.

Thus, non-invasive procedures for providing heat to internal tumors have had difficulties in achieving substantial specific and selective treatment.

Hyperthermia, which can be produced from an RF or microwave source, applies heat to tissue but does not exceed 45 degrees C so that normal cells survive. In thermotherapy, heat energy of greater than 45 degrees C is applied,

resulting in histological damage, desiccation and the denaturization of proteins. Hyperthermia has been applied more recently for therapy of malignant tumors. In hyperthermia, it is desirable to induce a state of hyperthermia that is localized by interstitial current heating to a specific area while concurrently insuring  
5 minimum thermal damage to healthy surrounding tissue. Often, the tumor is located subcutaneously and addressing the tumor requires either surgery, endoscopic procedures or external radiation. It is difficult to externally induce hyperthermia in deep body tissue because current density is diluted due to its absorption by healthy tissue. Additionally, a portion of the RF energy is  
10 reflected at the muscle/fat and bone interfaces which adds to the problem of depositing a known quantity of energy directly on a small tumor.

Attempts to use interstitial local hyperthermia have not proven to be very successful. Results have often produced nonuniform temperatures throughout  
15 the tumor. It is believed that tumor mass reduction by hyperthermia is related the thermal dose. Thermal dose is the minimum effective temperature applied throughout the tumor mass for a defined period of time. Because blood flow is the major mechanism of heat loss for tumors being heated, and blood flow varies throughout the tumor, more even heating of tumor tissue is needed to ensure  
20 more effective treatment.

The same is true for ablation of the tumor itself through the use of RF energy. Different methods have been utilized for the RF ablation of masses such as tumors. Instead of heating the tumor it is ablated through the application of  
25 energy. This process has been difficult to achieve due to a variety of factors including, (i) positioning of the RF ablation electrodes to effectively ablate all of the mass, (ii) introduction of the RF ablation electrodes to the tumor site and (iii) controlled delivery and monitoring of RF energy to achieve successful ablation without damage to non-tumor tissue.

There have been a number of different treatment methods and devices for minimally invasively treating tumors. One such example is an endoscope that produces RF hyperthermia in tumors, as disclosed in U.S. Patent No. 4,920,978. A microwave endoscope device is described in U.S. Patent No. 4,409,993. In U.S. Patent No. 4,920,978, an endoscope for RF hyperthermia is disclosed.

In U.S. Patent No. 4,763,671, a minimally invasive procedure utilizes two catheters that are inserted interstitially into the tumor. The catheters are placed within the tumor volume and each is connect to a high frequency power source.

In U.S. Patent No. 4,565,200, an electrode system is described in which a single entrance tract cannula is used to introduce an electrode into a selected body site.

However, as an effective treatment device, electrodes must be properly positioned relative to the tumor. After the electrodes are positioned, it is then desirable to have controlled application and deposition of RF energy to ablate the tumor. This reduces destruction of healthy tissue.

There is a need for a RF tumor treatment apparatus that is useful for minimally invasive procedures. It would be desirable for such a device to surround the exterior of the tumor with treatment electrodes, defining a controlled ablation volume, and subsequently the electrodes deliver a controlled amount of RF energy. Additionally, there is a need for a device with infusion capabilities during a pre-ablation step, and after ablation the surrounding tissue can be preconditioned with electromagnetic ("EM") energy at hyperthermia temperatures less than 45 degrees. This would provide for the synergistic affects of chemotherapy and the instillation of a variety of fluids at the tumor site after local ablation and hyperthermia.

### SUMMARY OF THE INVENTION

An object of the invention is to provide an RF tissue ablation apparatus which ablates a desired tissue site, such as a tumor, in a minimally invasive manner.

5

Another object of the invention is to provide an RF tissue ablation apparatus which includes a selectable plurality of retractable electrodes which are advanced from a delivery catheter to define an ablation volume.

10

A further object of the invention is to provide an RF tissue ablation apparatus which includes a plurality of electrodes that are retractable to and from a delivery catheter. The electrodes are at least partially positioned in the delivery catheter in a non-deployed state, and become distended in a deployed state when advanced out a distal end of the delivery catheter, defining the ablation volume.

15

Another object of the invention is to provide an RF tissue ablation apparatus with deployed electrodes having a first section with a first radius of curvature, and a second section, that extends beyond the first section, having a second radius of curvature or a substantially linear geometry.

20

Yet another object of the invention is to provide an RF tissue ablation apparatus with deployed electrodes with two or more radii of curvature.

25

Still another object of the invention is to provide an RF tissue ablation apparatus with deployed electrodes having at least one radii of curvature in two or more planes.

30

A further object of the invention is to provide an RF tissue ablation apparatus with at least one deployed electrode that has one curved section located near a distal end of the delivery catheter, and a non-curved section

extending beyond the curved section of the deployed electrode. The ablation apparatus also includes at least one deployed electrode with at least two radii of curvature.

5 Yet another object of the invention is to provide a tissue ablation apparatus with a plurality of retractable electrodes, each deployed electrode has at least one curved section located near a distal end of a delivery catheter, and a non-curved section which extends beyond the curved section of the deployed electrode.

10

These and other objects are attained with a tissue ablation apparatus that includes a delivery catheter, with distal and proximal ends. A handle is attached to the proximal end of the delivery catheter. An electrode deployment apparatus is positioned at least partially in the delivery catheter. It includes a plurality of electrodes that are retractable in and out of the catheter's distal end. The electrodes are in a non-deployed state when they are positioned within the delivery catheter. As they are advanced out the distal end of the catheter they become deployed, and define an ablation volume. Each electrode has a first section with a first radius of curvature, and a second section, extending beyond the first section, having a second radius of curvature or a substantially linear geometry.

15

20

25

Alternatively, each deployed electrode has at least two radii of curvature that are formed when the needle is advanced through the delivery catheter's distal end and becomes positioned at a selected tissue site.

In another embodiment, each deployed electrode has at least one radius of curvature in two or more planes. Further, the electrode deployment apparatus can include at least one deployed electrode having at least radii of curvature, and

at least one deployed electrode with at least one radius of curvature in two or more planes.

5 In a further embodiment, the electrode deployment apparatus has at least one deployed electrode with at least one curved section that is located near the distal end of the delivery catheter, and a non-curved section which extends beyond the curved section of the deployed electrode. The electrode deployment apparatus also has at least one deployed electrode with at least two radii of curvature.

10 In another embodiment of the invention, each deployed electrode has at least one curved section located near the distal end of the delivery catheter, and a non-curved section that extends beyond the curved section of the deployed electrode.

15 An electrode template can be positioned at the distal end of the delivery catheter. It assists in guiding the deployment of the electrodes to a surrounding relationship at an exterior of a selected mass in a tissue. The electrodes can be hollow. An adjustable electrode insulator can be positioned in an adjacent, surrounding relationship to all or some of the electrodes. The electrode insulator is adjustable, and capable of being advanced and retracted along the electrodes in order to define an electrode conductive surface.

20 The electrode deployment apparatus can include a cam which advances and retracts the electrodes in and out of the delivery catheter's distal end. Optionally included in the delivery catheter are one or more guide tubes associated with one or more electrodes. The guide tubes are positioned at the delivery catheter's distal end.

Sources of infusing mediums, including but not limited to electrolytic and chemotherapeutic solutions, can be associated with the hollow electrodes. Electrodes can have sharpened, tapered ends in order to assist their introduction through tissue, and advancement to the selected tissue site.

5

The electrode deployment apparatus is removable from the delivery catheter. An obturator is initially positioned within the delivery catheter. It can have a sharpened distal end. The delivery catheter can be advanced percutaneously to an internal body organ, or site, with the obturator positioned in the delivery catheter. Once positioned, the obturator is removed, and the electrode deployment apparatus is inserted into the delivery catheter. The electrodes are in non-deployed states, and preferably compacted or spring-loaded, while positioned within the delivery catheter. They are made of a material with sufficient strength so that as the electrodes emerge from the delivery catheter's distal end they are deployed three dimensionally, in a lateral direction away from the periphery of the delivery catheter's distal end. The electrodes continue their lateral movement until the force applied by the tissue causes the needles to change their direction of travel.

20

Each electrode now has either, (i) a first section with a first radius of curvature, and a second section, extending beyond the first section, having a second radius of curvature or a substantially linear section, (ii) two radii of curvature, (iii) one radius of curvature in two or more planes, or (iv) a combination of two radii of curvature with one of them in two or more planes. Additionally, the electrode deployment apparatus can include one or more of these deployed geometries for the different electrodes in the plurality. It is not necessary that every electrode have the same deployed geometry.

25

After the electrodes are positioned around a mass, such as a tumor, a variety of solutions, including but not limited to electrolytic fluids, can be introduced through the electrodes to the mass in a pre-ablation step. RF energy

30

is applied, and the mass is desiccated. In a post-ablation procedure, a chemotherapeutic agent can then be introduced to the site, and the electrodes are then retracted back into the introducing catheter. The entire ablative apparatus can be removed, or additional ablative treatments be conducted.

### BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a perspective view of the tissue ablation apparatus of the invention, including a delivery catheter, handle, and deployed electrodes.

5                Figure 2 is a cross-sectional view of the tissue ablation apparatus of the invention illustrated in Figure 1.

Figure 3 is a perspective view of an electrode of the invention with two radii of curvature.

10              Figure 4 is a perspective view of an electrode of the invention with one radius of curvature in three planes.

15              Figure 5 is a perspective view of an electrode of the invention with one curved section, positioned close to the distal end of the delivery catheter, and a linear section.

20              Figure 6 is a perspective view of an electrode of the invention with one curved section, positioned close to the distal end of the delivery catheter, a generally first linear section, and then a second linear section that continues laterally with regard to the first linear section.

25              Figure 7 is a cross-section view of a delivery catheter associated with the invention, with guide tubes positioned at the distal end of the delivery catheter.

Figure 8 is a cross-sectional view of an electrode of the invention.

Figure 9 is a perspective view of the tissue ablation apparatus of the invention shown in Figure 1, with the delivery catheter being introduced

percutaneously through the body and positioned at the exterior, or slightly piercing, a liver with a tumor to be ablated.

5 Figure 10 is a perspective view of the tissue ablation apparatus of the invention with an obturator positioned in the delivery catheter.

Figure 11 is a perspective view of the tissue ablation apparatus of the invention shown in Figure 10, positioned in the body adjacent to the liver, with the obturator removed.

10

Figure 12 is a perspective view of the tissue ablation apparatus of the invention shown in Figure 10, positioned in the body adjacent to the liver, and the electrode deployment apparatus, with an electrode template, is positioned in the delivery catheter in place of the obturator.

15

Figure 13 is a perspective view of the ablation apparatus of the invention, with deployed electrodes surrounding a tumor and defining an ablation volume.

20 Figure 14 is a perspective view of the tissue ablation apparatus of the invention shown in Figure 10, positioned in the body adjacent to the liver, with deployed electrodes surrounding a tumor and infusing a solution to the tumor site during a pre-ablation procedure.

25 Figure 15 is a perspective view of the tissue ablation apparatus of the invention shown in Figure 10, illustrating application of RF energy to the tumor.

Figure 16 is a perspective view of the tissue ablation apparatus of the invention, illustrating the electro-desiccation of the tumor.

5 Figure 18 illustrates bipolar ablation between electrodes of the invention.

10                    Figure 20 is a perspective view of an ablation system of the invention,  
including RF and ultrasound modules, and a monitor.

15 DETAILED DESCRIPTION

- 12 -

monopolar modes. When the electrodes are used in the bipolar mode, the ablative volume is substantially defined by the peripheries of the plurality of electrodes 20. In one embodiment, the cross-sectional width of the ablative volume is about 4 cm. However, it will be appreciated that different ablative volumes can be achieved with tissue ablation apparatus 10.

The ablative volume is first determined to define a mass, such as a tumor, to be ablated.

Electrodes 20 are placed in a surrounding relationship to a mass or tumor in a predetermined pattern for volumetric ablation. An imaging system is used to first define the volume of the tumor or selected mass. Suitable imaging systems include but are not limited to, ultrasound, computerized tomography (CT) scanning, X-ray film, X-ray fluoroscopy, magnetic resonance imaging, electromagnetic imaging, and the like. The use of such devices to define a volume of a tissue mass or a tumor is well known to those skilled in the art.

With regard to the use of ultrasound, an ultrasound transducer transmits ultrasound energy into a region of interest in a patient's body. The ultrasound energy is reflected by different organs and different tissue types. Reflected energy is sensed by the transducer, and the resulting electrical signal is processed to provide an image of the region of interest. In this way, the ablation volume is then ascertained, and the appropriate electrode deployment device is inserted into delivery catheter 12.

The ablative volume is substantially defined before ablation apparatus 10 is introduced to an ablative treatment position. This assists in the appropriate positioning of ablation apparatus 10. In this manner, the volume of ablated tissue is reduced and substantially limited to a defined mass or tumor, including a certain area surrounding such a tumor, that is well controlled and defined. A

small area around the tumor is ablated in order to ensure that all of the tumor is ablated.

With reference again to Figure 2, electrode sections 20(a) are in deployed states when they are introduced out of distal end 16. Although electrodes 20 are generally in a non-distended configuration in the non-deployed state while positioned in delivery catheter 12, they can also be distended. Generally, electrode sections 20(b) are in retained positions while they are non-deployed. This is achieved by a variety of methods including but not limited to, (i) the electrodes are pre-sprung, confined in delivery catheter 12, and only become sprung (expanded) as they are released from delivery catheter 12, (ii) the electrodes are made of a memory metal, as explained in further detail below, (iii) the electrodes are made of a selectable electrode material which gives them an expanded shape outside of delivery catheter 12, or (iv) delivery catheter 12 includes guide tubes which serve to confine electrodes 12 within delivery catheter 12 and guide their direction of travel outside of the catheter to form the desired, expanded ablation volume. As shown in Figure 2, electrodes 20 are pre-sprung while retained in delivery catheter 12. This is the non-deployed position. As they are advanced out of delivery catheter 12 and into tissue, electrodes 20 become deployed and begin to "fan" out from distal end 16, moving in a lateral direction relative to a longitudinal axis of delivery catheter 12. As deployed electrodes 20 continue their advancement, the area of the fan increases and extends beyond the diameter of distal end 16.

Significantly, each electrode 20 is distended in a deployed position, and collectively, the deployed electrodes 20 define a volume of tissue that will be ablated. As previously mentioned, when it is desired to ablate a tumor, either benign or malignant, it is preferable to ablate an area that is slightly in excess to that defined by the exterior surface of the tumor. This improves the chances that all of the tumor is eradicated.

Deployed electrodes 20 can have a variety of different deployed geometries including but not limited to, (i) a first section with a first radius of curvature, and a second section, extending beyond the first section, having a second radius of curvature or a substantially linear geometry, (ii) at least two radii of curvature, (iii) at least one radius of curvature in two or more planes, (iv) a curved section, with an elbow, that is located near distal end 16 of delivery catheter, and a non-curved section that extends beyond the curved section, or (v) a curved section near distal end 16, a first linear section, and then another curved section or a second linear section that is angled with regard to the first linear section. Deployed electrodes 20 need not be parallel with respect to each other. The plurality of deployed electrodes 20, which define a portion of the needle electrode deployment device, can all have the same deployed geometries, i.e., all with at least two radii of curvature, or a variety of geometries, i.e., one with two radii of curvature, a second one with one radius of curvature in two planes, and the rest a curved section near distal end 16 of delivery catheter 12 and a non-curved section beyond the curved section.

A cam 22, or other actuating device, can be positioned within delivery catheter and used to advance and retract electrodes 20 in and out of delivery catheter 12. The actual movement of cam can be controlled at handle 18. Suitable cams are of conventional design, well known to those skilled in the art.

The different geometric configurations of electrodes 20 are illustrated in Figures 3 through 6. In Figure 3, electrode 20 has a first radius of curvature 20(c) and a second radius of curvature 20(d). It can include more than two radii of curvature. As shown in Figure 4, electrode 20 has at least one radius of curvature which extends to three planes. In Figure 5, each electrode has a first curved section 20(e) which is near distal end 16 of delivery catheter 12. A first generally linear section 20(f) extends beyond curved section 20(e), and the two meet at an elbow 20(g). The electrodes 20 can serve as anodes and cathodes.

The plurality of electrodes 20 can have linear sections 20(f) that are generally parallel to each other, or they can be non-parallel. Figure 6 illustrates an electrode 20 that includes a first curved section 20(e) positioned near distal end 16 of delivery catheter 12, a first linear section 20(f), and a second linear section 20(h) which extends beyond first linear section 20(f). Section 20(h) can be linear, curved, or a combination of the two. The plurality of electrodes 20 illustrated in Figure 6 can have parallel or non-parallel first linear sections 20(f).

In one embodiment of the invention, electrodes 20 are spring-loaded, and compacted in their non-deployed positions. As electrodes 20 are advanced out of distal end 16 of delivery catheter 12, they become deployed and fan out. Electrodes 20 continue this fanning out direction until the resistance of the tissue overcomes the strength of the material forming electrode 20. This causes electrode 20 to bend and move in a direction inward relative to its initial outward fanning direction. The bending creates curved sections 20(c) and 20(d) of Figure 3, and can also result in the formation of the other electrode 20 geometries of Figures 4, 5 and 6. The extent of electrode 20 fan like travel is dependent on the strength of the material from which it is made. Suitable electrode materials include stainless steel, platinum, gold, silver, copper and other electromagnetic conducting materials including conductive polymers. Preferably, electrode 20 is made of stainless steel or nickel titanium and has dimensions of about 27 to 14 gauge.

In one embodiment, electrode 20 is made of a memory metal, such as nickel titanium, commercially available from Raychem Corporation, Menlo Park, California. Additionally, a resistive heating element can be positioned in an interior lumen of electrode 20. Resistive heating element can be made of a suitable metal that transfers heat to electrode 20, causing deployed electrode 20 to become deflected when the temperature of electrode 20 reaches a level that causes the electrode material, such as a memory metal, to deflect, as is well

known in the art. Not all of electrode 20 need be made of a memory metal. It is possible that only that distal end portion of electrode 20, which is introduced into tissue, be made of the memory metal in order to effect the desired deployed geometrical configuration. Additionally, mechanical devices, including but not limited to steering wires, can be attached to the distal end of electrode 20 to cause it to become directed, deflected and move about in a desired direction about the tissue, until it reaches its final resting position to ablate a tissue mass.

Optionally included in the delivery catheter are one or more guide tubes 24, Figure 7, which serve to direct the expansion of electrodes 20 in the fan pattern as they are advanced out of distal end 16 of the delivery catheter 12. Guide tubes 24 can be made of stainless steel, spring steel and thermal plastics including but not limited to nylon and polyesters, and are of sufficient size and length to accommodate the electrodes to a specific site in the body.

Figure 8 illustrates one embodiment of electrode 20 with a sharpened distal end 24. By including a tapered, or piercing end 24, the advancement of electrode 20 through tissue is easier. Electrode 20 can be segmented, and include a plurality of fluid distribution ports 26, which can be evenly formed around all or only a portion of electrode 20. Fluid distribution ports 26 are formed in electrode 20 when it is hollow and permit the introduction and flow of a variety of fluidic mediums through electrode 20 to a desired tissue site. Such fluidic mediums include, but are not limited to, electrolytic solutions, pastes or gels, as well as chemotherapeutic agents. Examples of suitable conductive gels are carboxymethyl cellulose gels made from aqueous electrolyte solutions such as physiological saline solutions, and the like.

The size of fluid distribution ports 26 can vary, depending on the size and shape of electrode 20. Also associated with electrode 20 is an adjustable insulator sleeve 28 that is slidable along an exterior surface of electrode 20. Insulator sleeve 28 is advanced and retracted along electrode 20 in order to

define the size of a conductive surface of electrode 20. Insulator sleeve 28 is actuated at handle 18 by the physician, and its position along electrode 20 is controlled. When electrode 20 moves out of delivery catheter 12 and into tissue, insulator sleeve 28 can be positioned around electrode 20 as it moves its way  
5 through the tissue. Alternatively, insulator sleeve 28 can be advanced along a desired length of electrode 20 after electrode 20 has been positioned around a targeted mass to be ablated. Insulator sleeve is thus capable of advancing through tissue along with electrode 20, or it can move through tissue without electrode 20 providing the source of movement. Thus, the desired ablation  
10 volume is defined by deployed electrodes 20, as well as the positioning of insulator sleeve 28 on each electrode. In this manner, a very precise ablation volume is created. Suitable materials that form insulator sleeve include but are not limited to nylon, polyimides, other thermoplastics, and the like.

15 Figure 9 illustrates a percutaneous application of tissue ablation apparatus 10. Tissue ablation apparatus 10 can be used percutaneously to introduce electrodes 20 to the selected tissue mass or tumor. Electrodes 20 can remain in their non-deployed positions while being introduced percutaneously into the body, and delivered to a selected organ which contains the selected mass  
20 to be ablated. Delivery catheter 12 is removable from handle 18. When it is removed, electrode deployment device (the plurality of electrodes 20) can be inserted and removed from delivery catheter 12. An obturator 30 is inserted into delivery catheter 12 initially if a percutaneous procedure is to be performed. As shown in Figure 10, obturator 30 can have a sharpened distal end 32 that pierces  
25 tissue and assists the introduction of delivery catheter 12 to a selected tissue site. The selected tissue site can be a body organ with a tumor or other mass, or the actual tumor itself.

Obturator 30 is then removed from delivery catheter 12 (Figure 11).  
30 Electrode deployment device is then inserted into delivery catheter 12, and the

catheter is then reattached to handle 18 (Figure 12). As illustrated in Figure 12, electrode deployment device can optionally include an electrode template 34 to guide the deployment of electrodes 20 to a surrounding relationship at an exterior of a selected mass in the tissue.

5

Electrodes 20 are then advanced out of distal end 16 of delivery catheter 12, and become deployed to form a desired ablative volume which surrounds the mass. In Figure 13, delivery catheter 12 is positioned adjacent to the liver. Electrode deployment device is introduced into delivery catheter 12 with electrode template 34. Electrode deployment device now pierces the liver, and cam 22 advances electrodes 20 out of delivery catheter 12 into deployed positions. Each individual electrode 20 pierces the liver and travels through it until it is positioned in a surrounding relationship to the tumor. The ablative volume is selectable, and determined first by imaging the area to be ablated. The ablative volume is defined by the peripheries of all of the deployed electrodes 20 that surround the exterior of the tumor. Once the volume of ablation is determined, then an electrode set is selected which will become deployed to define the ablation volume. A variety of different factors are important in creating an ablation volume. Primarily, different electrodes 20 will have various degrees of deployment, based on type of electrode material, the level of pre-springing of the electrodes and the geometric configuration of the electrodes in their deployed states. Tissue ablation apparatus 10 permits different electrode 20 sets to be inserted into delivery catheter 12, in order to define a variety of ablation volumes.

25

Prior to ablation of the tumor, a pre-ablation step can be performed. A variety of different solutions, including electrolytic solutions such as saline, can be introduced to the tumor site, as shown in Figure 14. Figure 15 illustrates the application of RF energy to the tumor. Electrode insulator 28 is positioned on portions of electrodes 20 where there will be no ablation. This further defines

30

the ablation volume. The actual electro-desiccation of the tumor, or other targeted masses or tissues, is shown in Figure 16. Again, deployed electrodes 20, with their electrode insulators 28 positioned along sections of the electrodes, define the ablation volume, and the resulting amount of mass that is desiccated.

5

Optionally following desiccation, electrodes 20 can introduce a variety of solutions in a post-ablation process. This step is illustrated in Figure 17. Suitable solutions include but are not limited to chemotherapeutic agents.

10

Figure 8 illustrates tissue ablation apparatus 10 operated in a bipolar mode. Its monopolar operation is shown in Figure 19. Each of the plurality of electrodes 20 can play different roles in the ablation process. There can be polarity shifting between the different electrodes.

15

A tissue ablation system 36, which can be modular, is shown in Figure 20 and can include a display 38. Tissue ablation system 36 can also include an RF energy source, microwave source, ultrasound source, visualization devices such as cameras and VCR's, electrolytic and chemotherapeutic solution sources, and a controller which can be used to monitor temperature or impedance. One of the  
20 deployed electrodes 20 can be a microwave antenna coupled to a microwave source. This electrode can initially be coupled to RF power source 42 and is then switched to the microwave source

20

25

Referring now to Figure 21, a power supply 40 delivers energy into RF power generator (source) 42 and then to electrodes 20 of tissue ablation apparatus 10. A multiplexer 46 measures current, voltage and temperature (at numerous temperature sensors which can be positioned on electrodes 20). Multiplexer 46 is driven by a controller 48, which can be a digital or analog controller, or a computer with software. When controller 48 is a computer, it  
30 can include a CPU coupled through a system bus. This system can include a

30

keyboard, disk drive, or other non-volatile memory systems, a display, and other peripherals, as known in the art. Also coupled to the bus are a program memory and a data memory.

5           An operator interface 50 includes operator controls 52 and display 38. Controller 48 is coupled to imaging systems, including ultrasound transducers, temperature sensors, and viewing optics and optical fibers, if included.

10           Current and voltage are used to calculate impedance. Diagnostics are done through ultrasound, CT scanning, or other methods known in the art. Imaging can be performed before, during and after treatment.

15           Temperature sensors measure voltage and current that is delivered. The output of these sensors is used by controller 48 to control the delivery of RF power. Controller 48 can also control temperature and power. The amount of RF energy

20           delivered controls the amount of power. A profile of power delivered can be incorporated in controller 38, as well as a pre-set amount of energy to be delivered can also be profiled.

25           Feedback can be the measurement of impedance or temperature, and occurs either at controller 48 or at electromagnetic energy source 42, e.g., RF or microwave, if it incorporates a controller. For impedance measurement, this can be achieved by supplying a small amount of non-ablation RF energy. Voltage and current are then measured.

30           Circuitry, software and feedback to controller 48 result in process control and are used to change, (i) power, including RF, ultrasound, and the like, (ii) the duty cycle (on-off and wattage), (iii) monopolar or bipolar energy delivery, (iv)

chemotherapeutic and electrolytic solution delivery, flow rate and pressure and  
(v) determine when ablation is completed through time, temperature and/or  
impedance. These process variables can be controlled and varied based on  
temperature monitored at multiple sites, and impedance to current flow that is  
5 monitored, indicating changes in current carrying capability of the tissue during  
the ablative process.

The foregoing description of preferred embodiments of the present  
invention has been provided for the purposes of illustration and description. It is  
10 not intended to be exhaustive or to limit the invention to the precise forms  
disclosed. Obviously, many modifications and variations will be apparent to  
practitioners skilled in this art. The embodiments were chosen and described in  
order to best explain the principles of the invention and its practical application,  
thereby enabling others skilled in the art to understand the invention for various  
15 embodiments and with various modifications as are suited to the particular use  
contemplated. It is intended that the scope of the invention be defined by the  
following claims and their equivalents.

What is claimed is:

**CLAIMS**

1. An ablation apparatus, comprising:  
an elongated member including a proximal end, a hollow lumen and a  
5 tissue piercing distal end;  
a first electrode positionable in the hollow lumen in a compacted state  
and advanceable from a distal portion of the elongated member in an expanded  
state in a lateral direction relative to a longitudinal axis of the elongated member,  
the first electrode including a tissue piercing distal end;  
10 a second electrode positionable in the hollow lumen in a compacted state  
and advanceable from a distal portion of the elongated member in an expanded  
state in a lateral direction relative to a longitudinal axis of the elongated member,  
the second electrode including a tissue piercing distal end; and  
an electrode advancement member coupled to the first and second  
15 electrodes and configured to advance the first and second electrodes through  
tissue to a selected tissue site, wherein each of the first and second electrodes  
includes at least one radius of curvature in the expanded state at the selected  
tissue site and configured to create a three-dimensional ablation.
- 20 2. An ablation apparatus, comprising:  
an elongated member including a proximal end, a hollow lumen and a  
distal end;  
an introducer member including a tissue piercing distal end, wherein the  
introducer member is configured to be removably positionable in the hollow  
25 lumen of the elongated member;  
a first electrode positionable in the hollow lumen in a compacted state  
and advanceable from the elongated member in an expanded state in a lateral  
direction relative to a longitudinal axis of the elongated member, the first  
electrode including a tissue piercing distal end;

a second electrode positionable in the hollow lumen in a compacted state and advanceable in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the second electrode including a tissue piercing distal end; and

5            an electrode advancement member coupled to the first and second electrodes and configured to advance the first and second electrodes through tissue to a selected tissue site, wherein each of the first and second electrodes includes at least one radius of curvature in the expanded state at the selected tissue site to create a three-dimensional ablation.

10

3.        An ablation apparatus, comprising:

an elongated member with a proximal end, a distal end and a hollow lumen;

15           a first electrode positionable in the hollow lumen in a compacted state and advanceable from the hollow lumen in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the first electrode including a tissue piercing distal end;

20           a second electrode positionable in the hollow lumen in a compacted state and advanceable in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the second electrode including a piercing distal end; and

25           wherein each electrode is in a compacted state when positioned in the hollow lumen and an expanded state when advanced from the hollow lumen to define an ablation volume between the deployed electrodes in the expanded state, each expanded electrode having at least one radii of curvature after advancement from the elongated member and positioned at a selected tissue site.

4.        An ablation apparatus, comprising:

an elongated member with a proximal end, a distal end and a hollow lumen;

5 a first electrode positionable in the hollow lumen in a compacted state and advanceable from the hollow lumen in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the first electrode including a piercing distal end;

10 a second electrode configured to be positioned in the hollow lumen in a compacted state and advanceable from the hollow lumen in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the second electrode including a piercing distal end; and

wherein each electrode is in a compacted state when positioned in the hollow lumen and an expanded state when advanced from the hollow lumen to surround a periphery of a selected tissue site, wherein each electrode has at least one radii of curvature when positioned at the selected tissue site.

15

5. An ablation apparatus, comprising:

an elongated member with a proximal end, a distal end and a hollow lumen;

20 a first electrode positionable in the hollow lumen in a compacted state and advanceable from the hollow lumen in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the first electrode including a piercing distal end;

25 a second electrode positionable in the hollow lumen in a compacted state and advanceable in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the second electrode including a piercing distal end; and

wherein each electrode is in a compacted state when positioned in the hollow lumen and an expanded state when advanced from the hollow lumen to define an ablation volume between the deployed electrodes in the expanded

state, each expanded electrode having at least two radii of curvature when positioned at a selected tissue site.

5           6.       The apparatus of claim 5, further comprising:  
an electrode advancement member coupled to the first and second  
electrodes to advance the first and second electrodes to the selected tissue site  
where the first and second electrodes are configured to create a three-  
dimensional ablation volume.

10           7.       The apparatus of claim 5, wherein the elongated member is  
configured to receive a fluidic medium.

            8.       The apparatus of claim 5, wherein the first electrode includes a  
hollow lumen configured to receive a fluidic medium.

15           9.       The apparatus of claim 5, further comprising:  
an insulator positioned in a surrounding relation to at least a portion of  
the first electrode.

20           10.      The apparatus of claim 5, further comprising:  
a source of a fluidic medium coupled to the elongated member.

            11.      The apparatus of claim 5, further comprising:  
a source of a chemotherapeutic agent coupled to the elongated member.

25           12.      The apparatus of claim 6, wherein the electrode advancement  
member is removable from the elongated member.

            13.      The apparatus of claim 5, further comprising:  
30           an obturator.

14. The apparatus of claim 13, wherein the obturator has a piercing distal end.

5 15. The apparatus of claim 13, wherein the obturator is positioned in the elongated member.

10 16. The apparatus of claim 13, wherein the obturator is removable from the elongated member after the elongated member is positioned at an internal body site, the electrode advancement member being positionable in the elongated member following a removal of the obturator from the elongated member.

15 17. An ablation apparatus, comprising:  
an elongated member with a proximal end, a distal end and a hollow lumen;  
a first electrode positionable in the hollow lumen in a compacted state and advanceable in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the first electrode including a piercing distal end; and  
20 a second electrode positionable in the hollow lumen in a compacted state and advanceable in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the second electrode including a piercing distal end, wherein each electrode is in a compacted state when positioned in the hollow lumen and in an expanded state when advanced from the  
25 hollow lumen to form an ablation volume between the deployed electrodes in the expanded state, each expanded electrode having at least one radii of curvature in two or more planes when positioned at a selected tissue site.

18. The apparatus of claim 17, further comprising:

an electrode deployment member coupled to the first and second electrodes and configured to advance the first and second electrodes three-dimensionally at a selected tissue site.

5           19.     The apparatus of claim 17, wherein the elongated member is configured to receive a fluidic medium.

          20.     The apparatus of claim 17, wherein the first electrode includes a hollow lumen configured to receive a fluidic medium.

10

          21.     An ablation apparatus, comprising:  
          an elongated member with a proximal end, a distal end and a hollow lumen;

          a first electrode configured to be positioned in the hollow lumen in a compacted state and advanced in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the first electrode including a piercing distal end;

15

          a second electrode configured to be positioned in the hollow lumen in a compacted state and advanced in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the second electrode including a piercing distal end; and

20

          wherein each electrode is in a compacted state when positioned in the hollow lumen and an expanded state when advanced from the hollow lumen to define an ablation volume between the deployed electrodes in the expanded state, each expanded electrode having at least one radii of curvature and a linear section after advancement from the elongated member and positioned at a selected tissue site.

25

          22.     The apparatus of claim 21, further comprising:

an electrode advancement member coupled to the first and second electrodes to advance the first and second electrodes to the selected tissue site where the first and second electrodes are configured to create a three-dimensional ablation volume.

5

23. The apparatus of claim 21, wherein the elongated member is configured to receive a fluidic medium.

10

24. The apparatus of claim 21, wherein the first electrode includes a hollow lumen configured to receive a fluidic medium.

15

25. An ablation apparatus, comprising:

an elongated member including a proximal end, a hollow lumen and a sufficient sharp distal end to pierce tissue;

a first electrode positionable in the hollow lumen in a compacted state and advanceable in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the first electrode including a tissue piercing distal end;

20

a second electrode positionable in the hollow lumen in a compacted state and advanceable in an expanded state in a lateral direction relative to a longitudinal axis of the elongated member, the second electrode including a tissue piercing distal end; and

25

an electrode advancement member coupled to the first and second electrodes, wherein each of the first and second electrodes includes at least one radius of curvature in the expanded state that reverses a direction of each electrode when the electrodes are advanced from the elongated member.

1/21

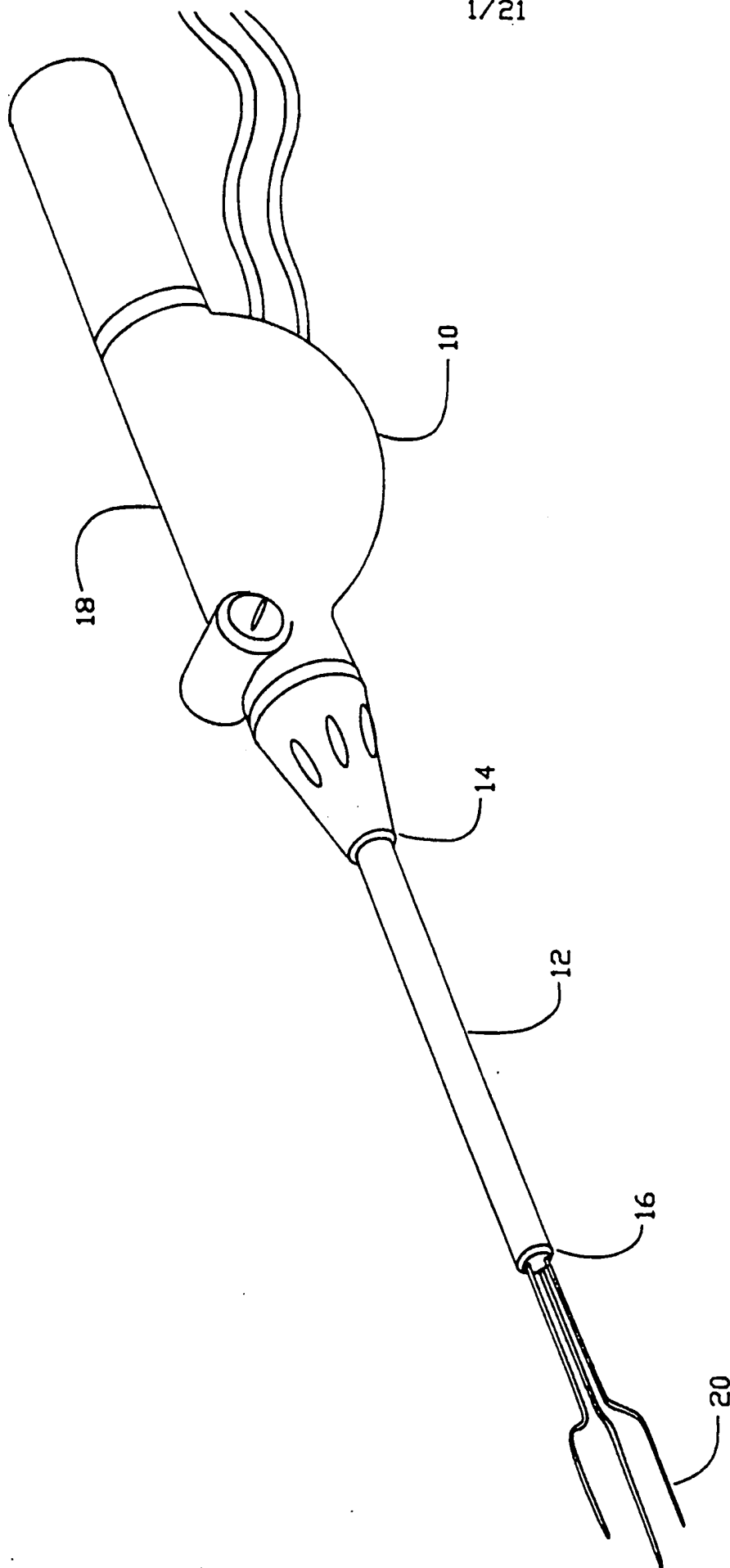


FIG. 1

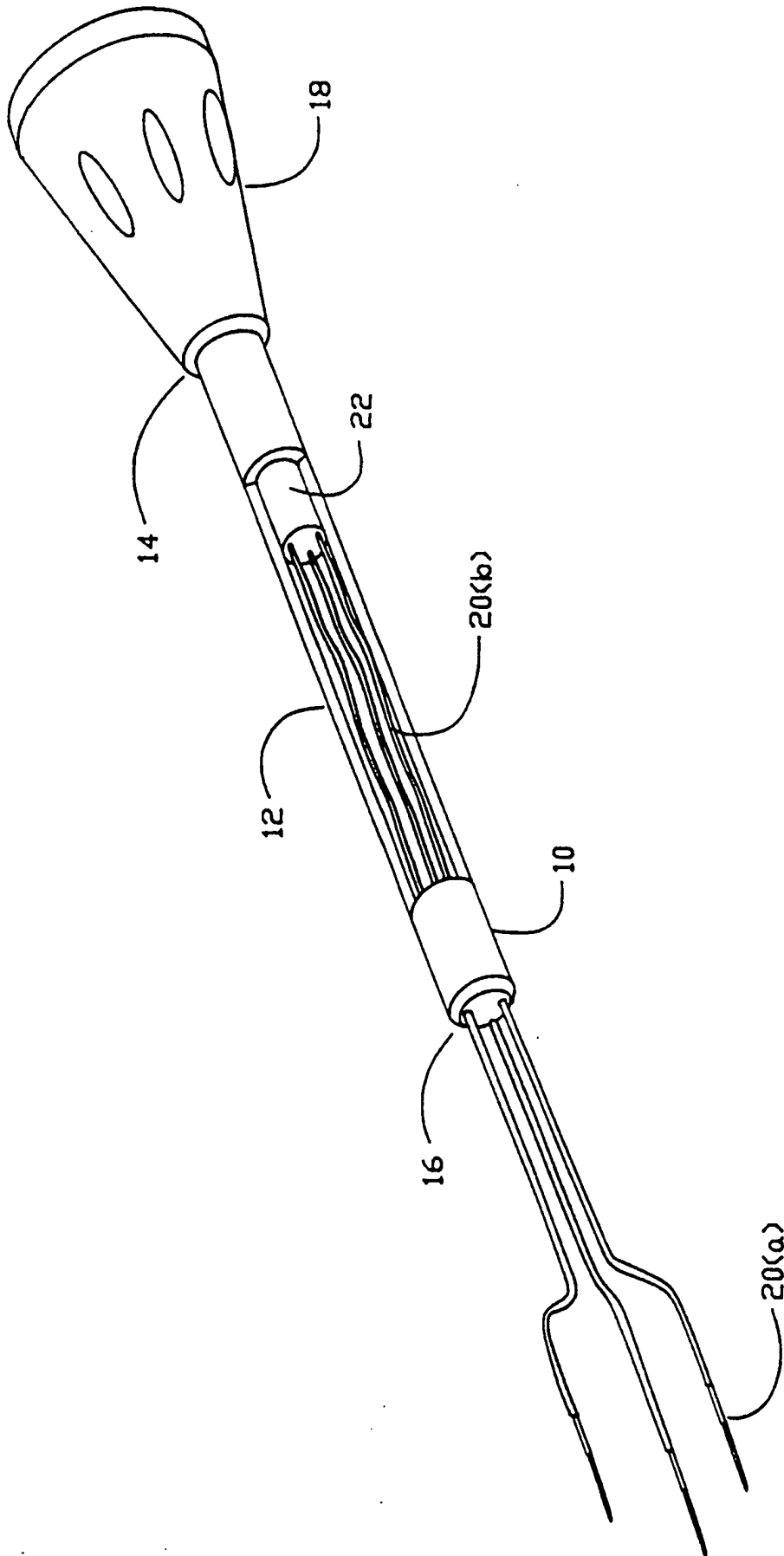


FIG. 2

3/21

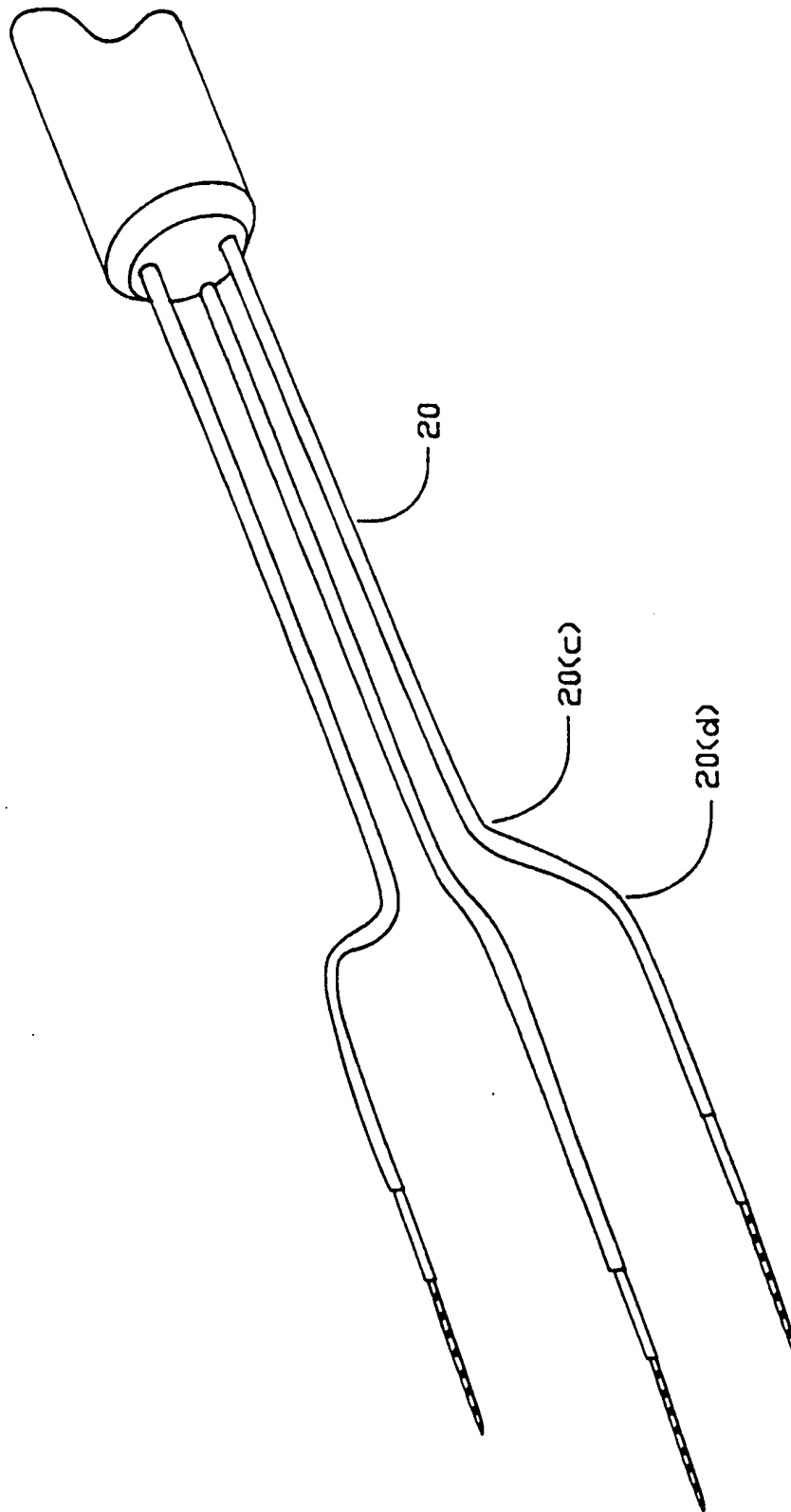
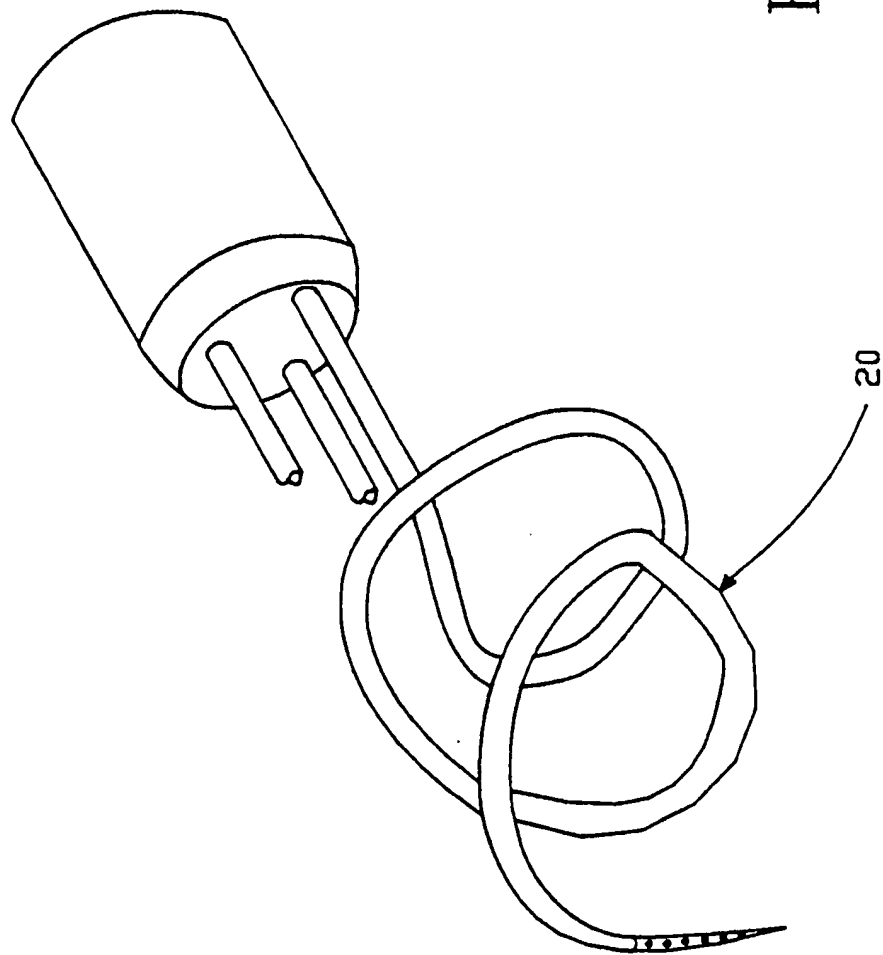


FIG. 3

FIG. 4



5/21

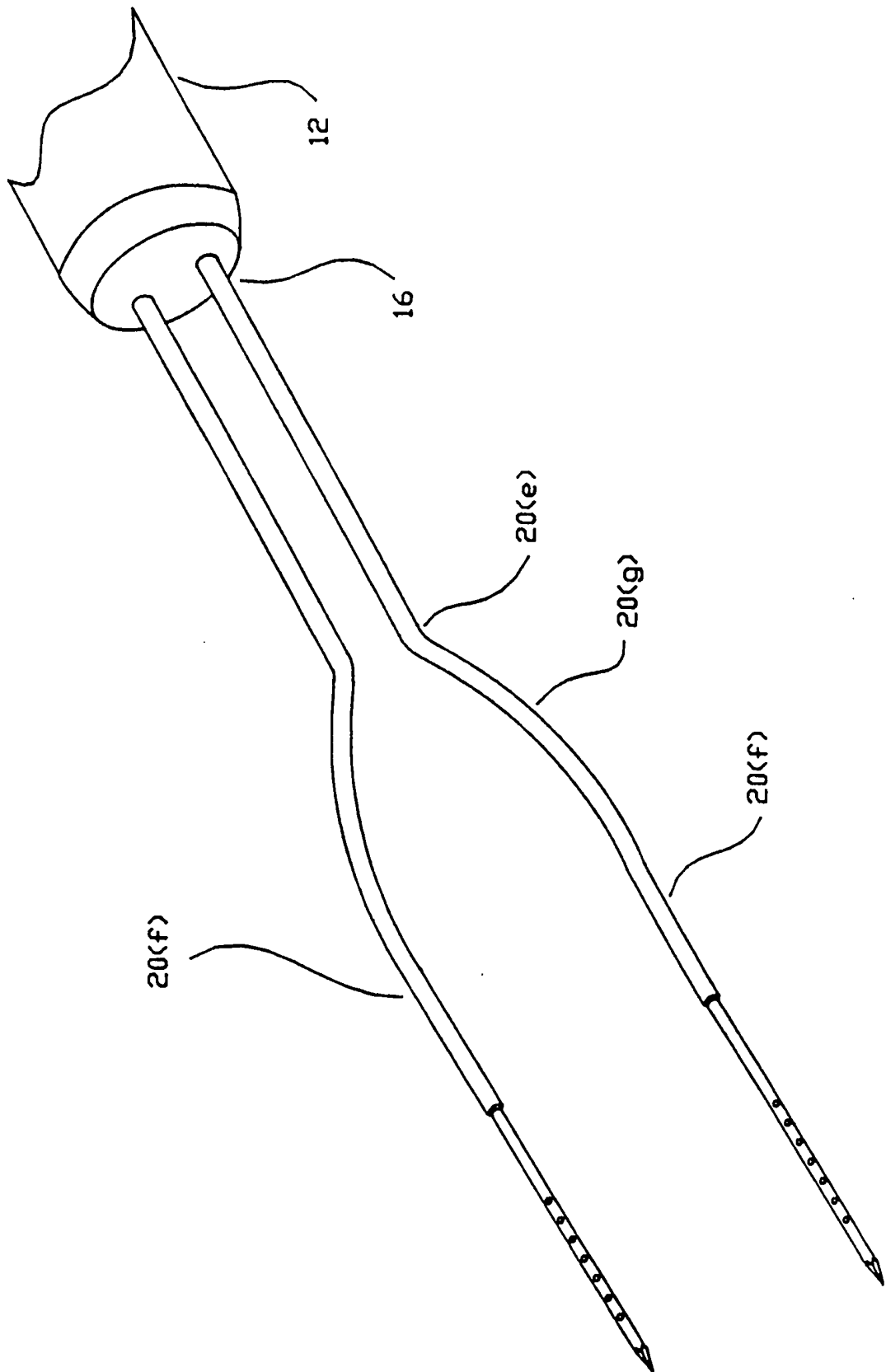


FIG. 5

6/21

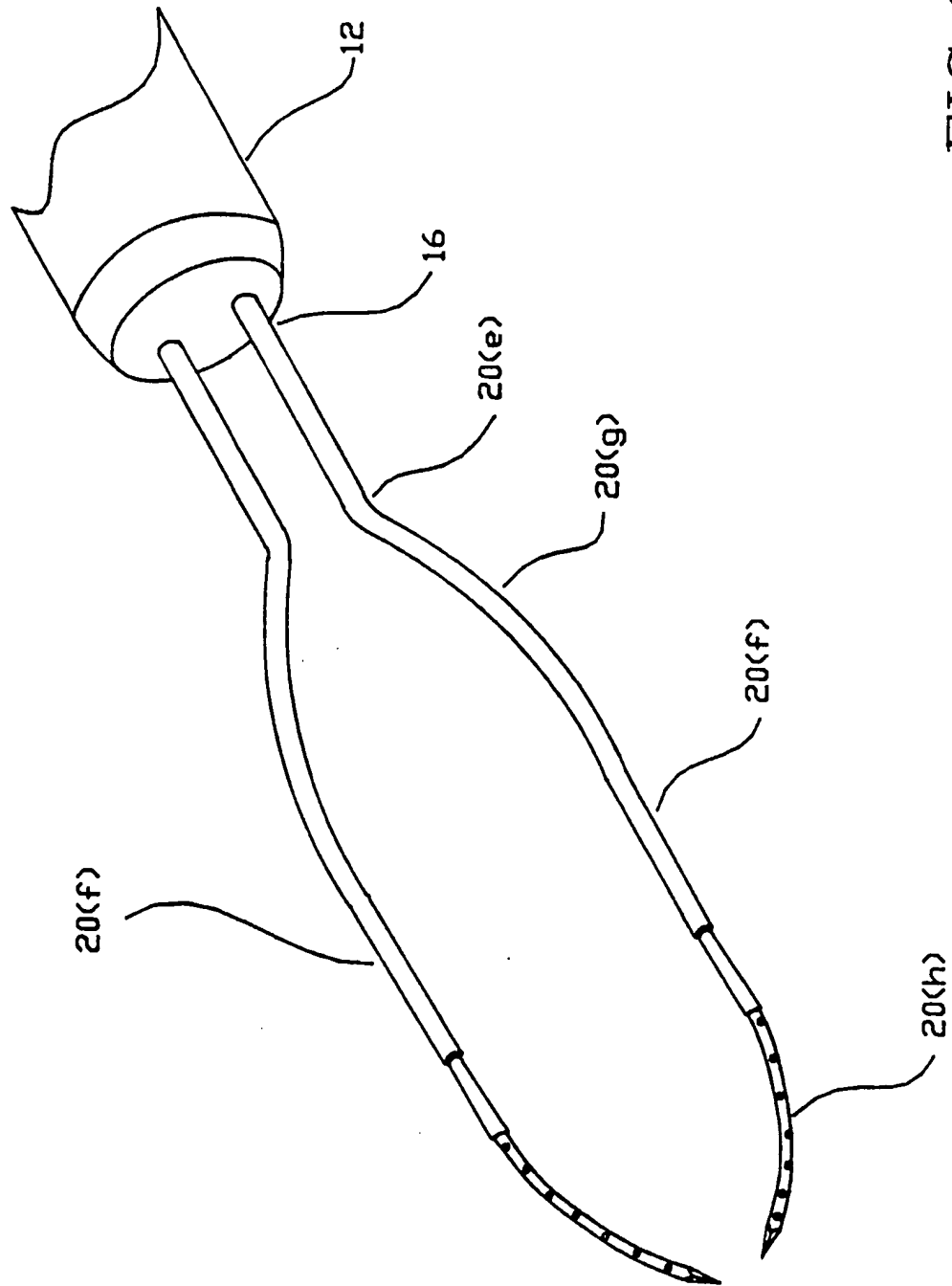


FIG. 6

7/21

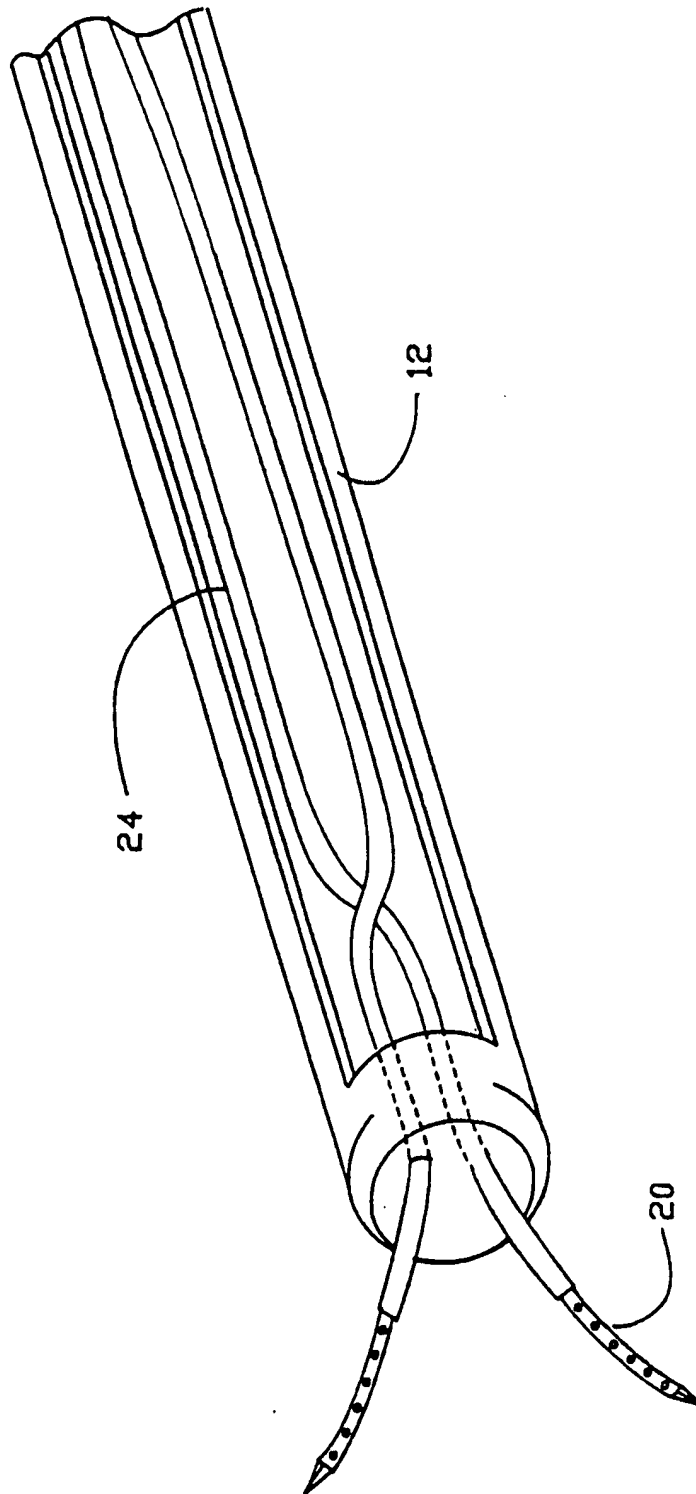


FIG. 7

8/21

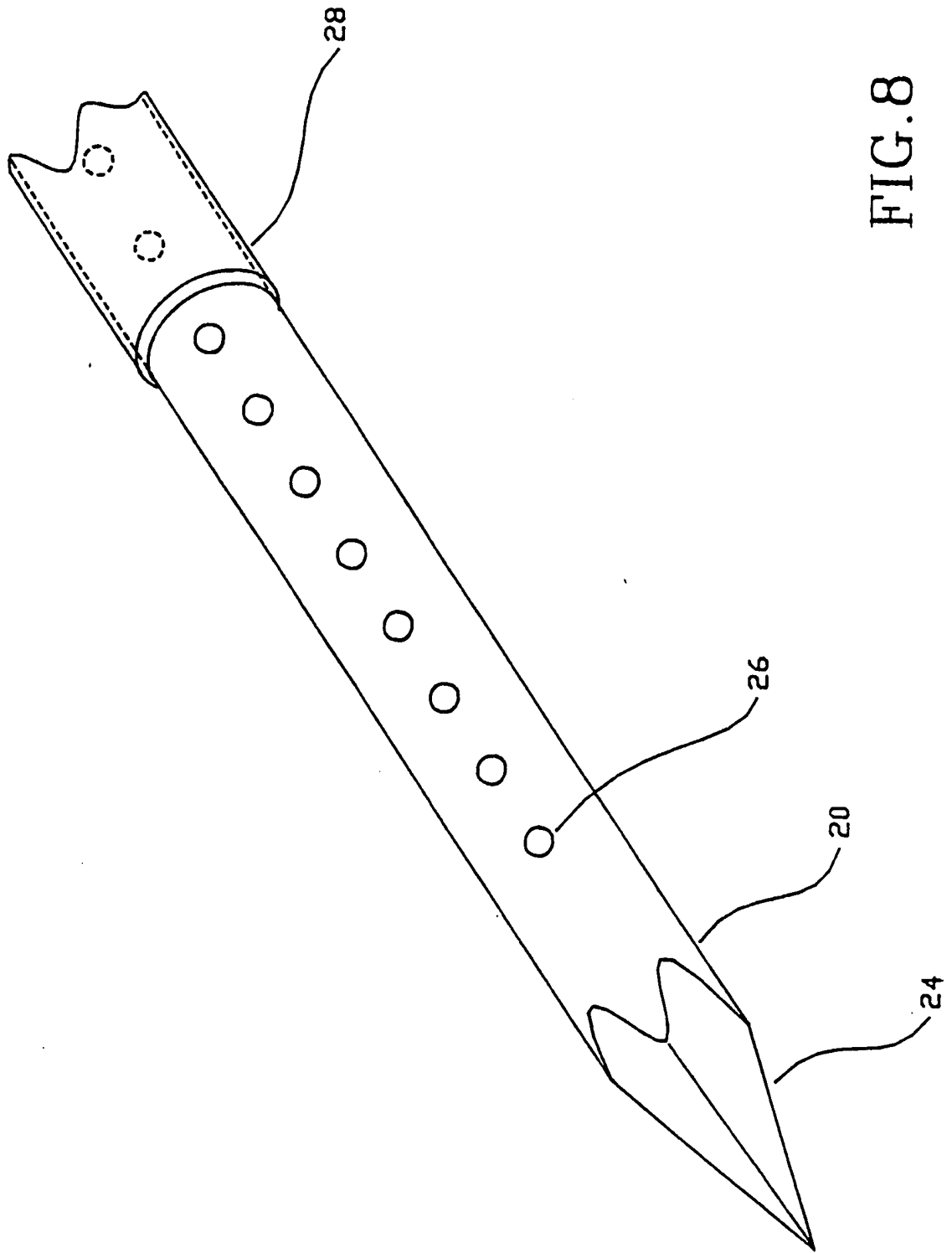


FIG. 8

9/21

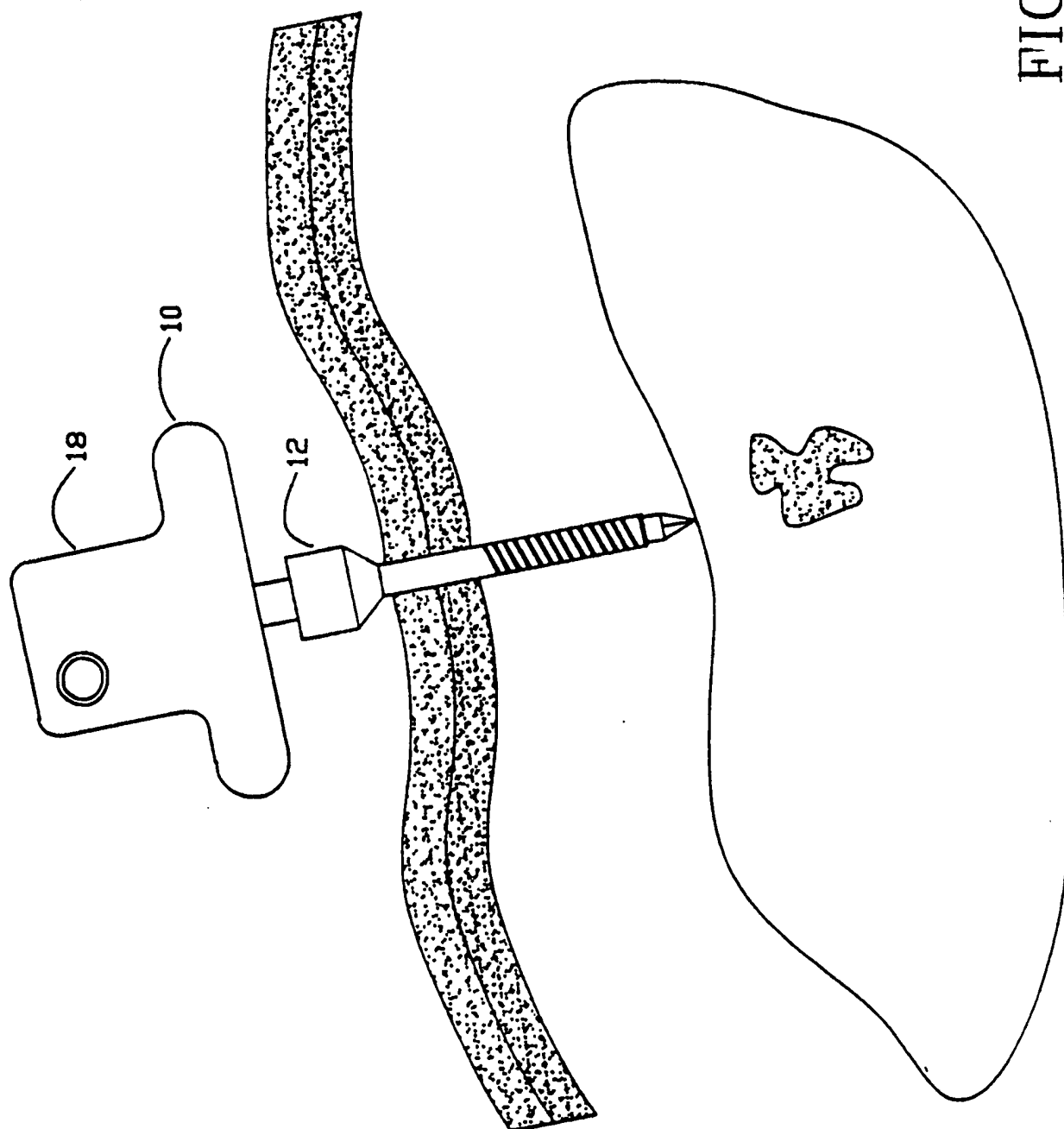


FIG. 9

10/21

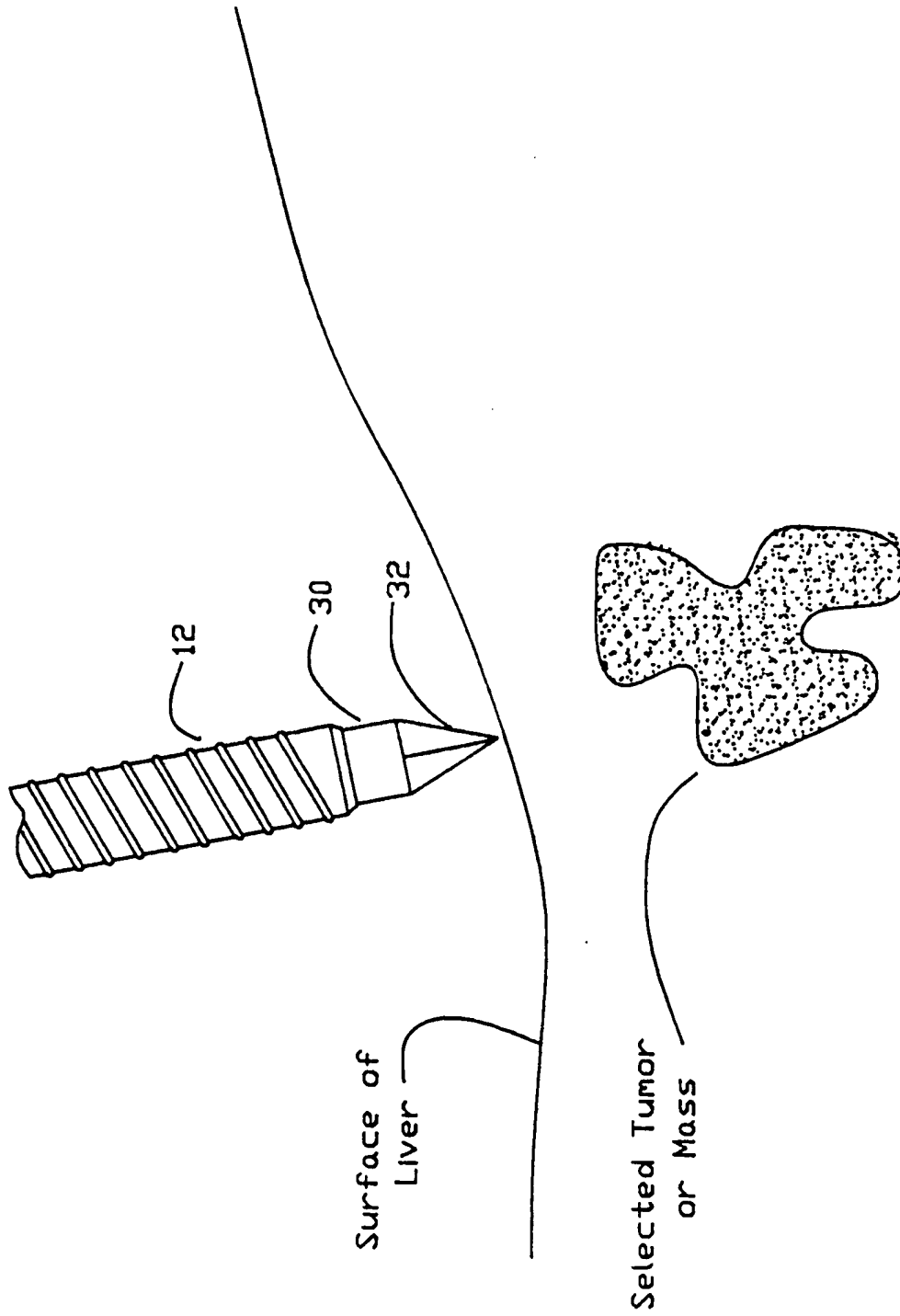
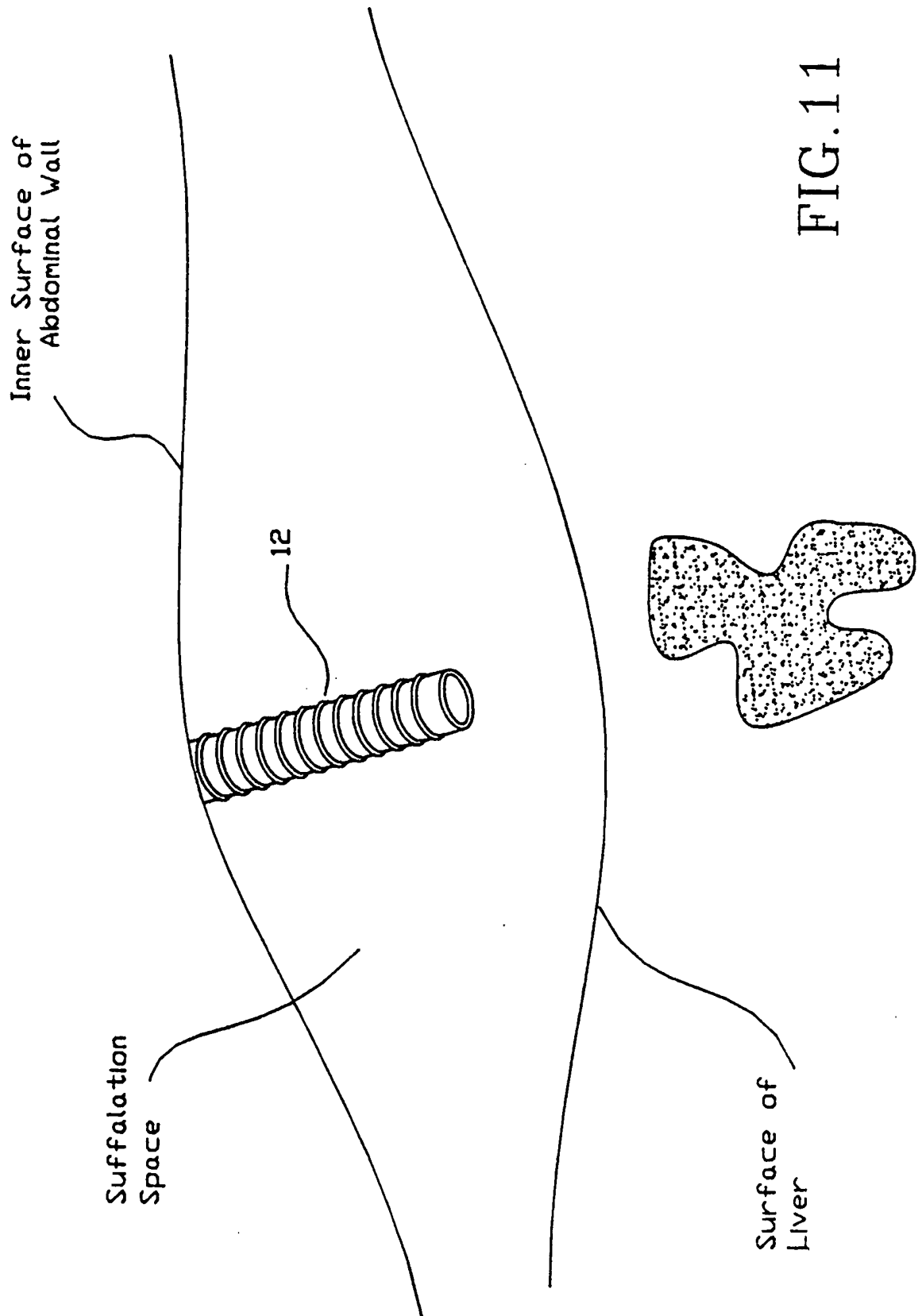


FIG. 10

11/21



12/21

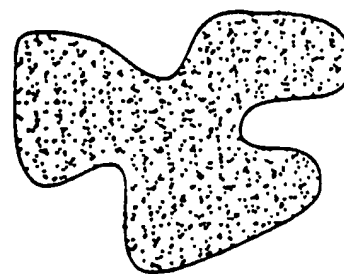
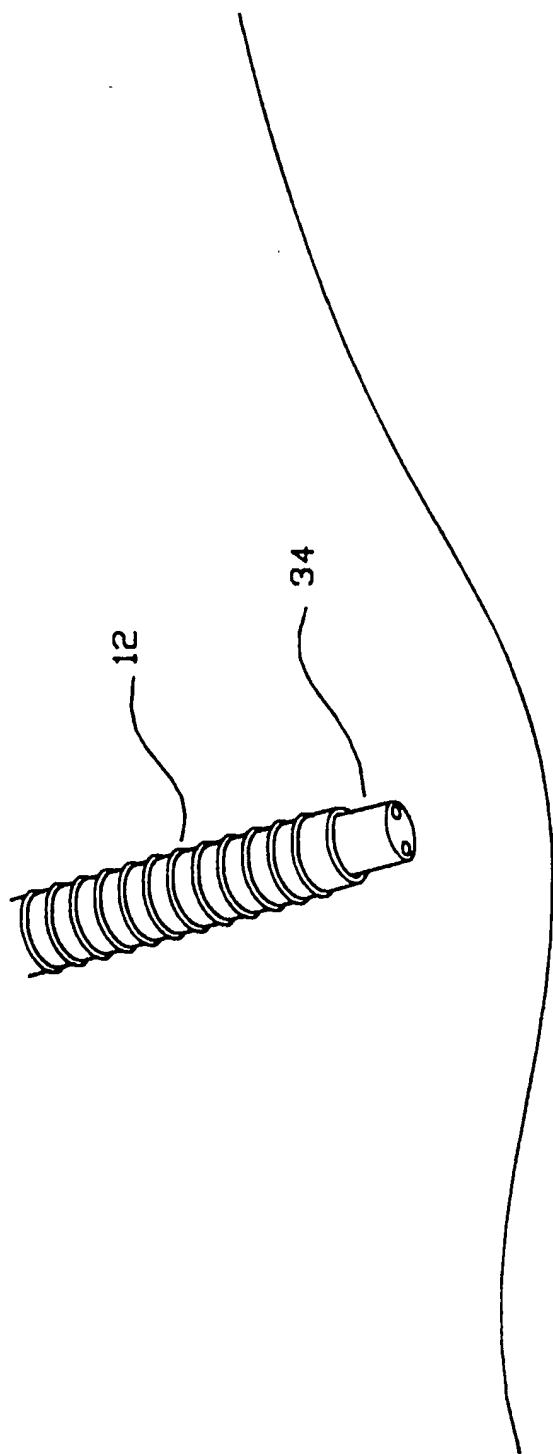


FIG. 12

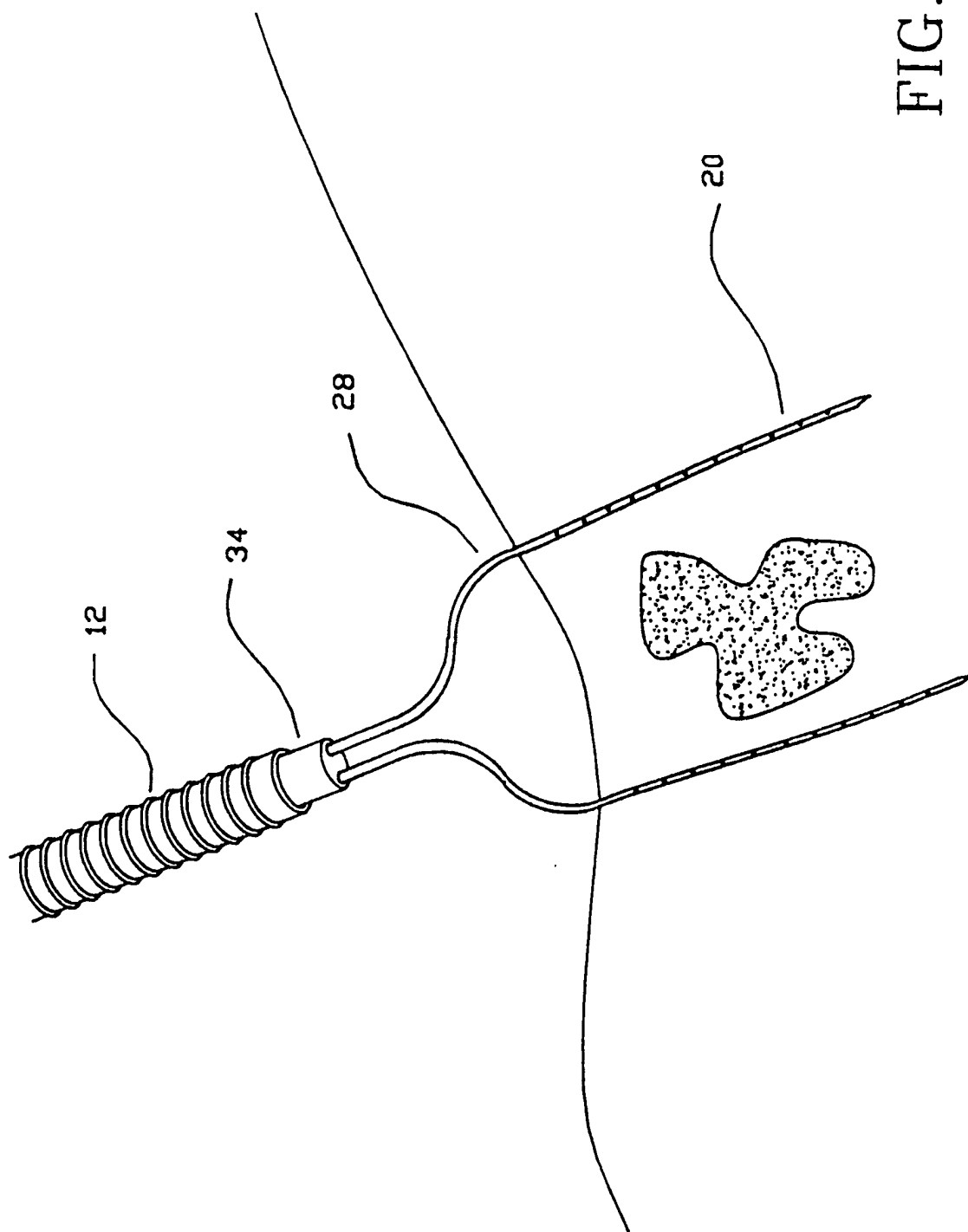


FIG. 13

14/21

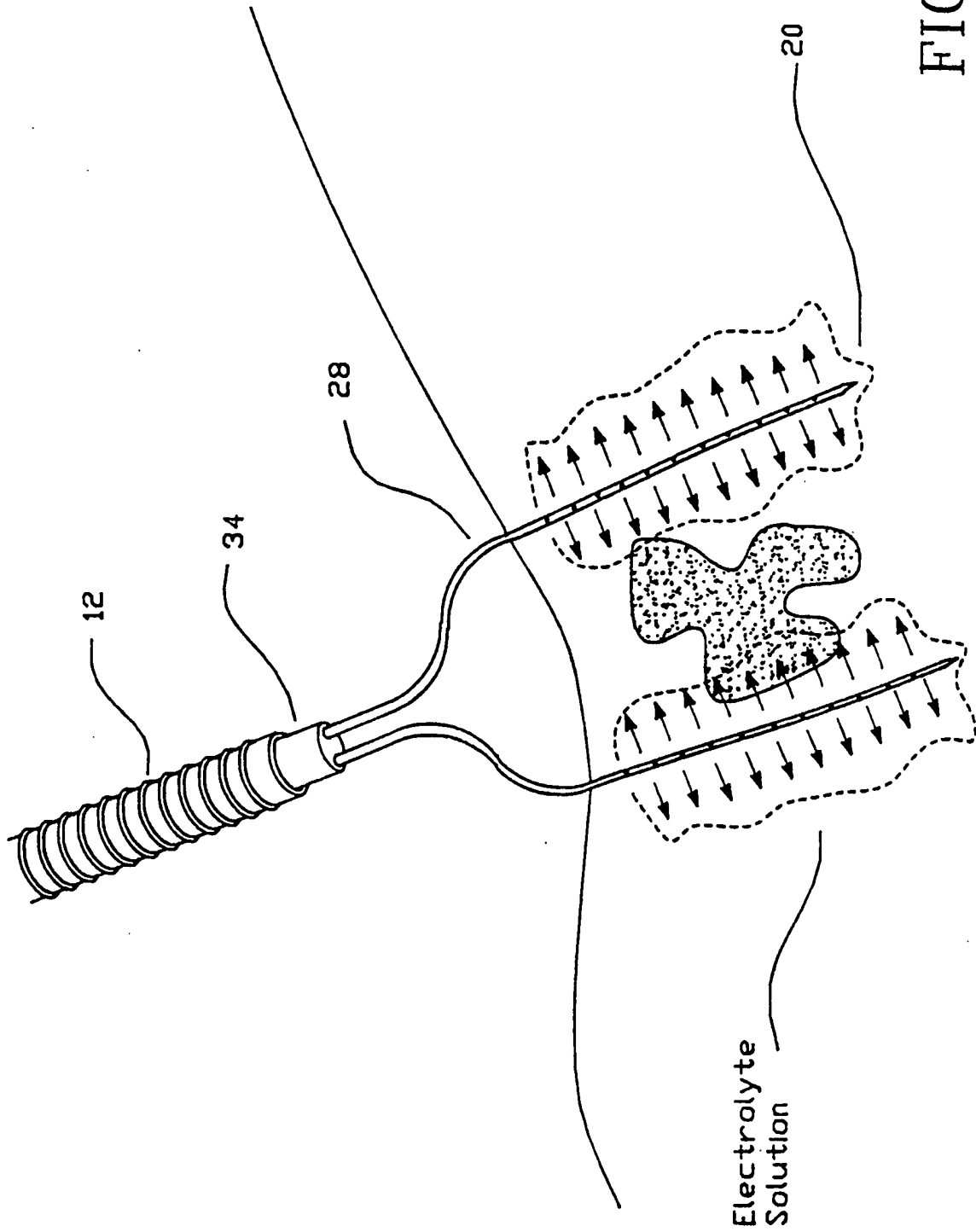


FIG. 14

15/21

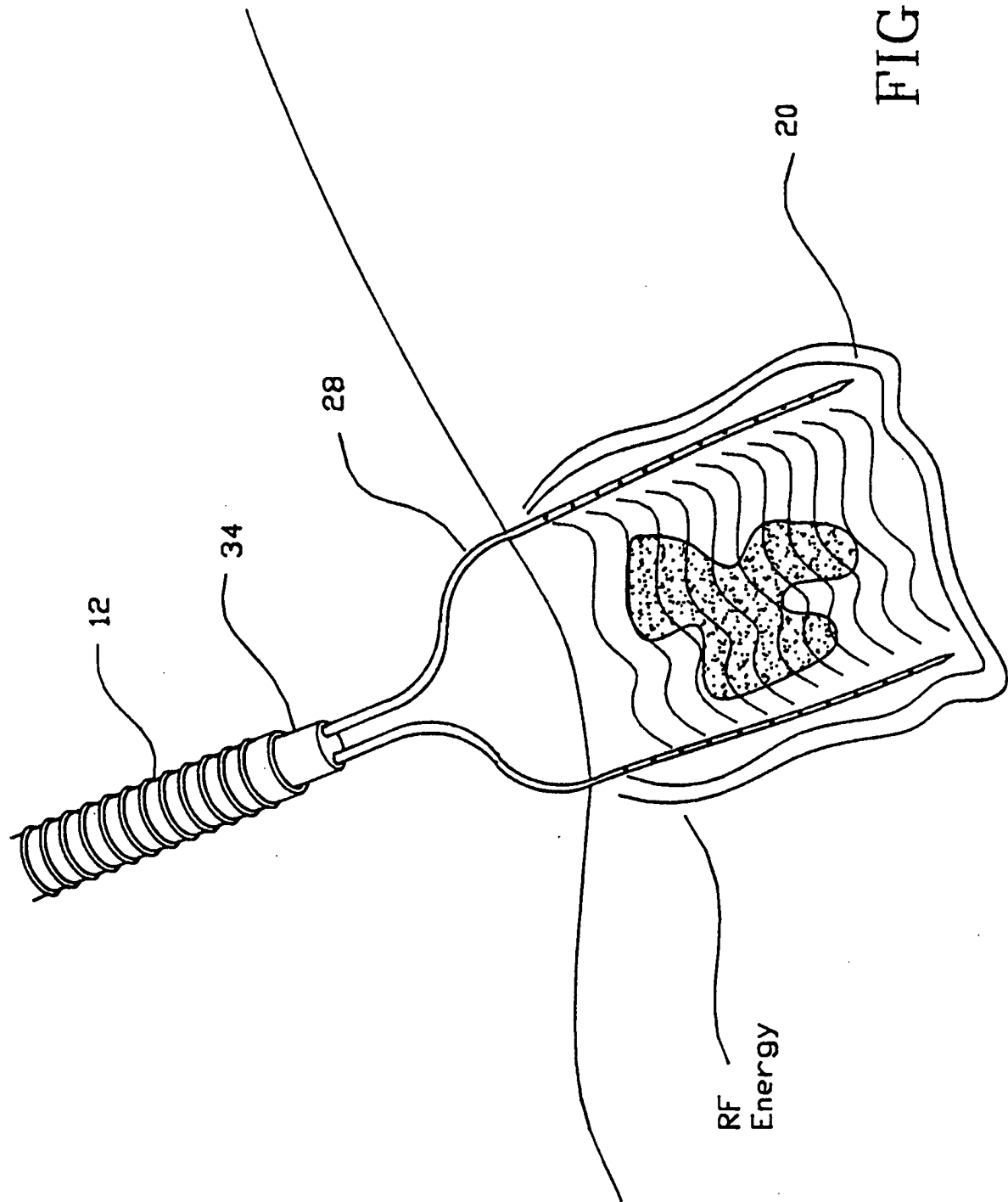


FIG. 15

16/21

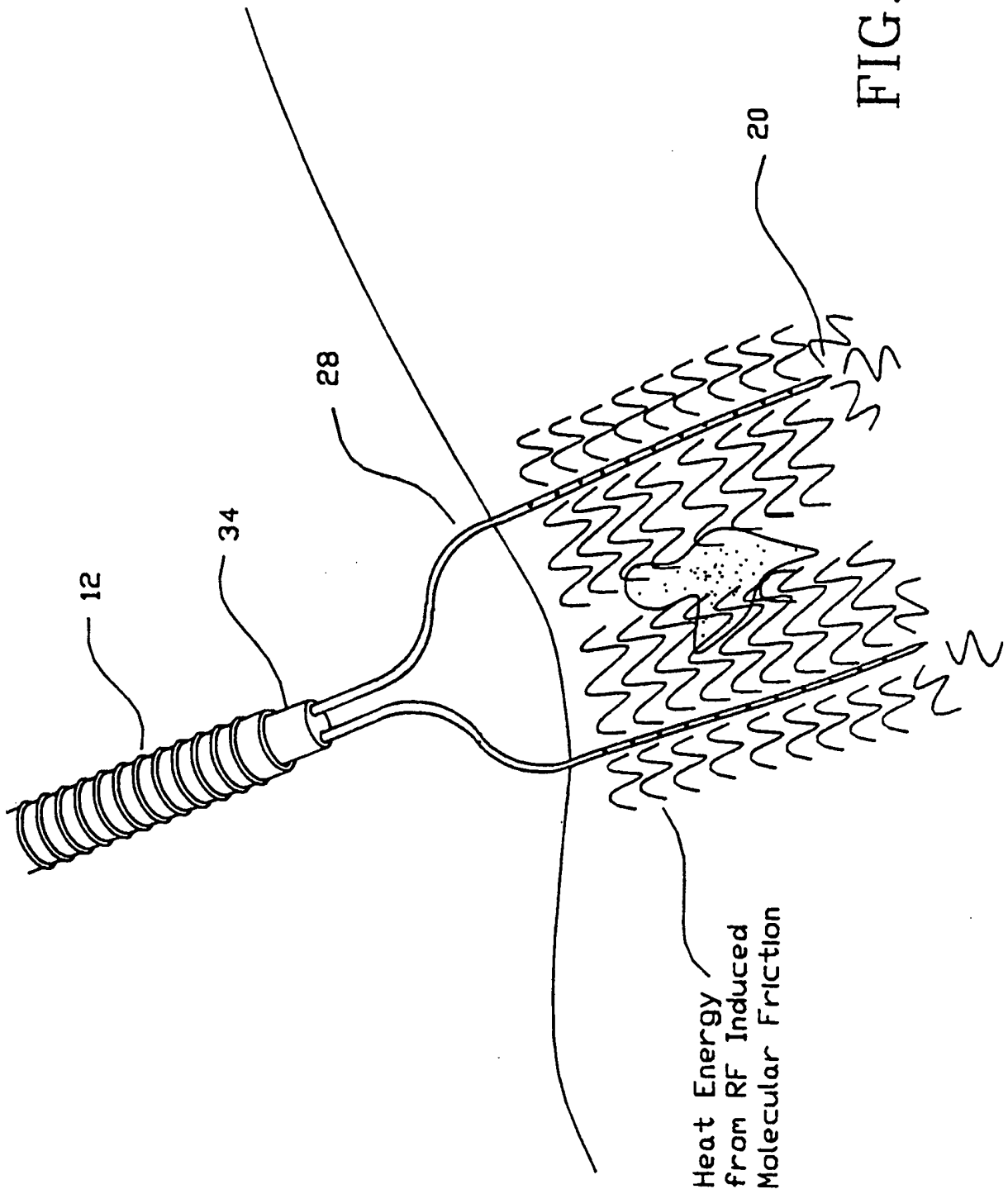


FIG. 16

17/21

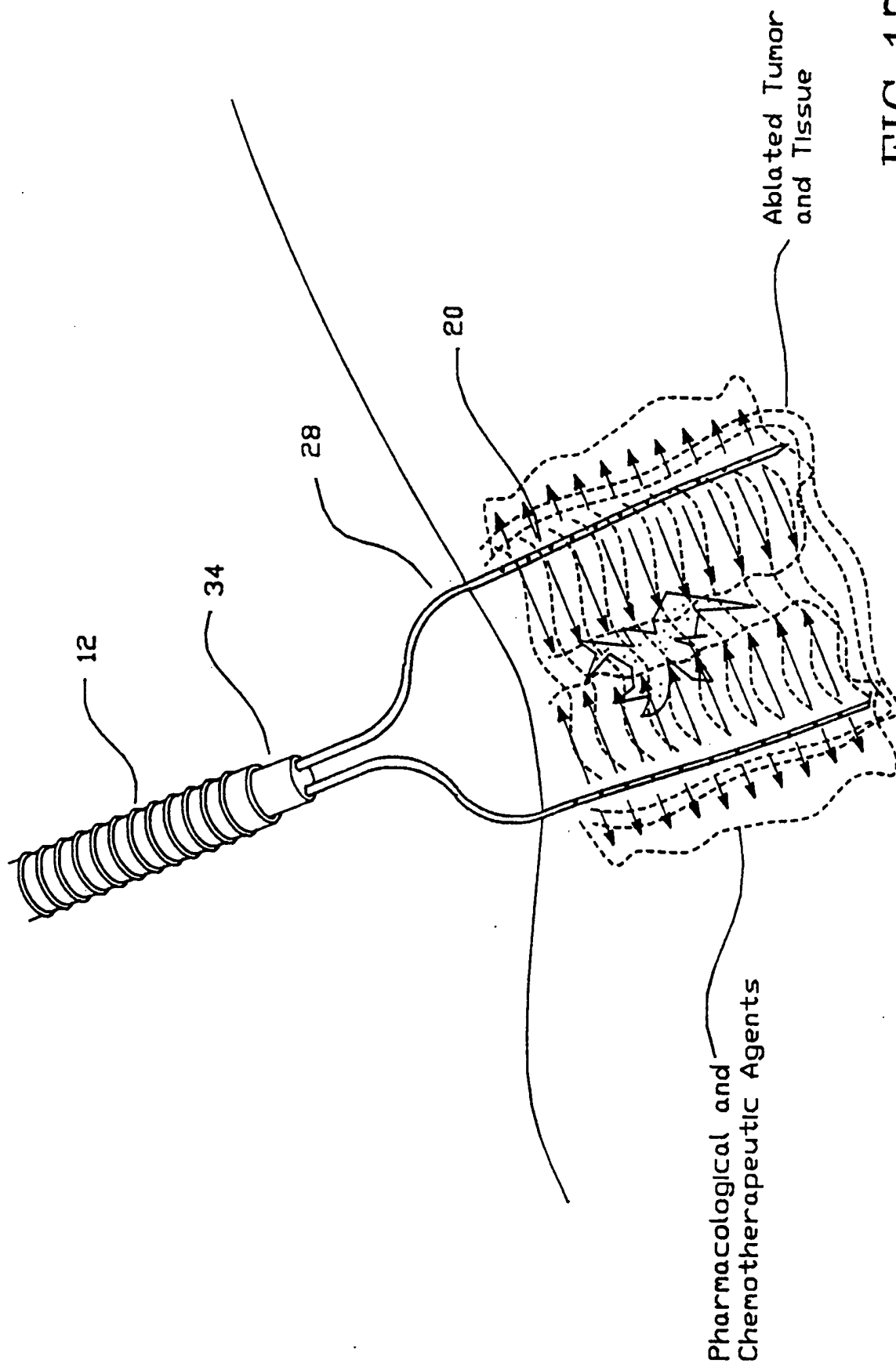


FIG. 17

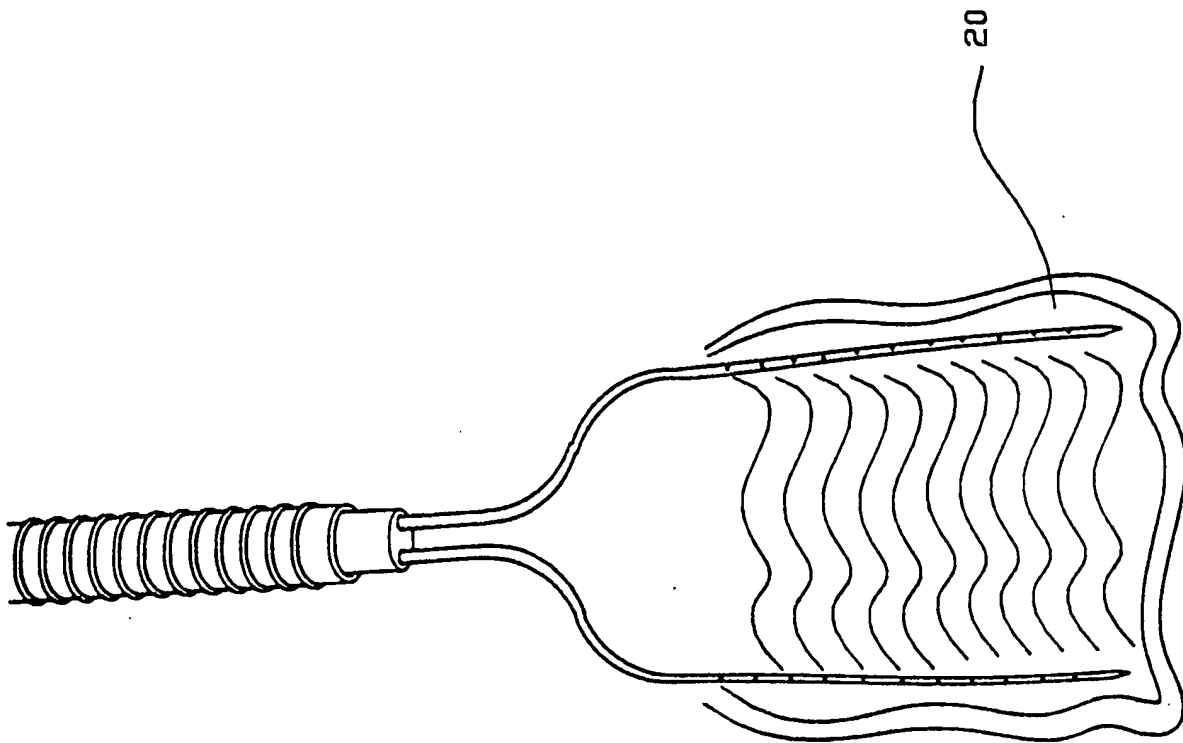


FIG. 18

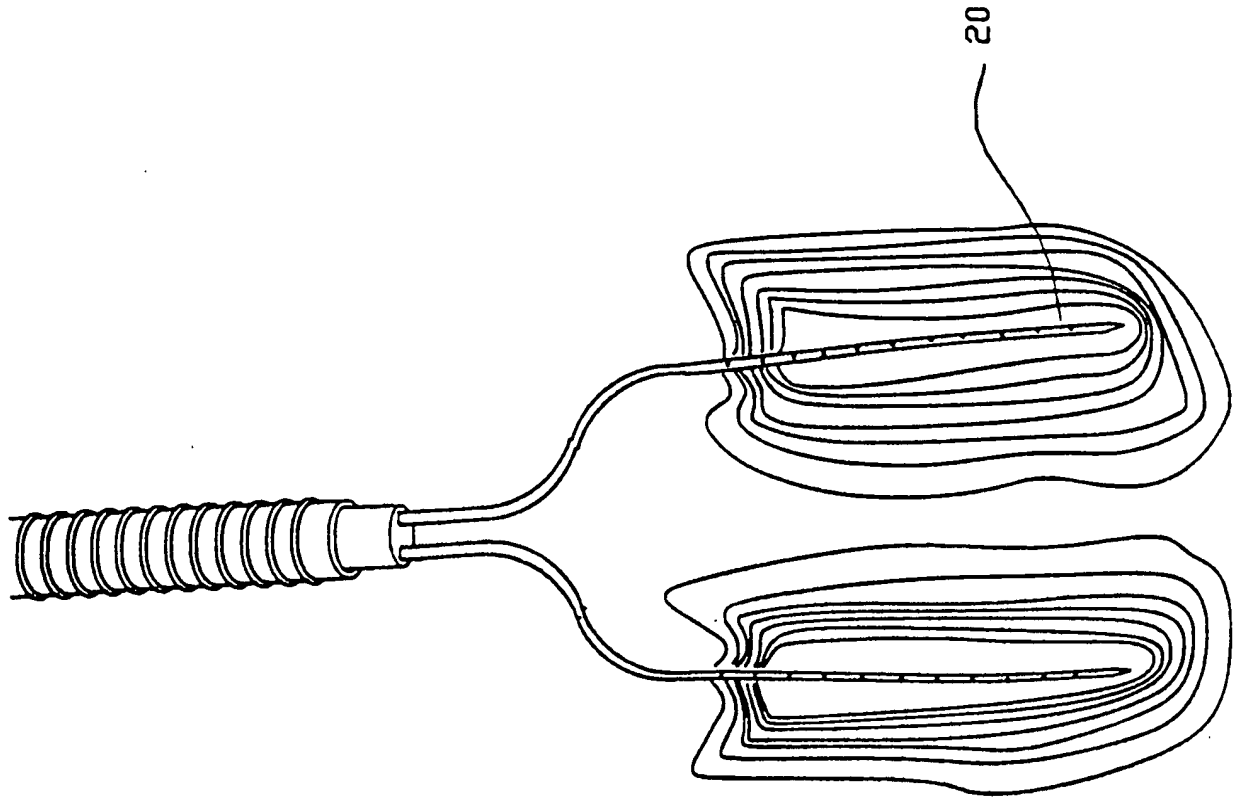
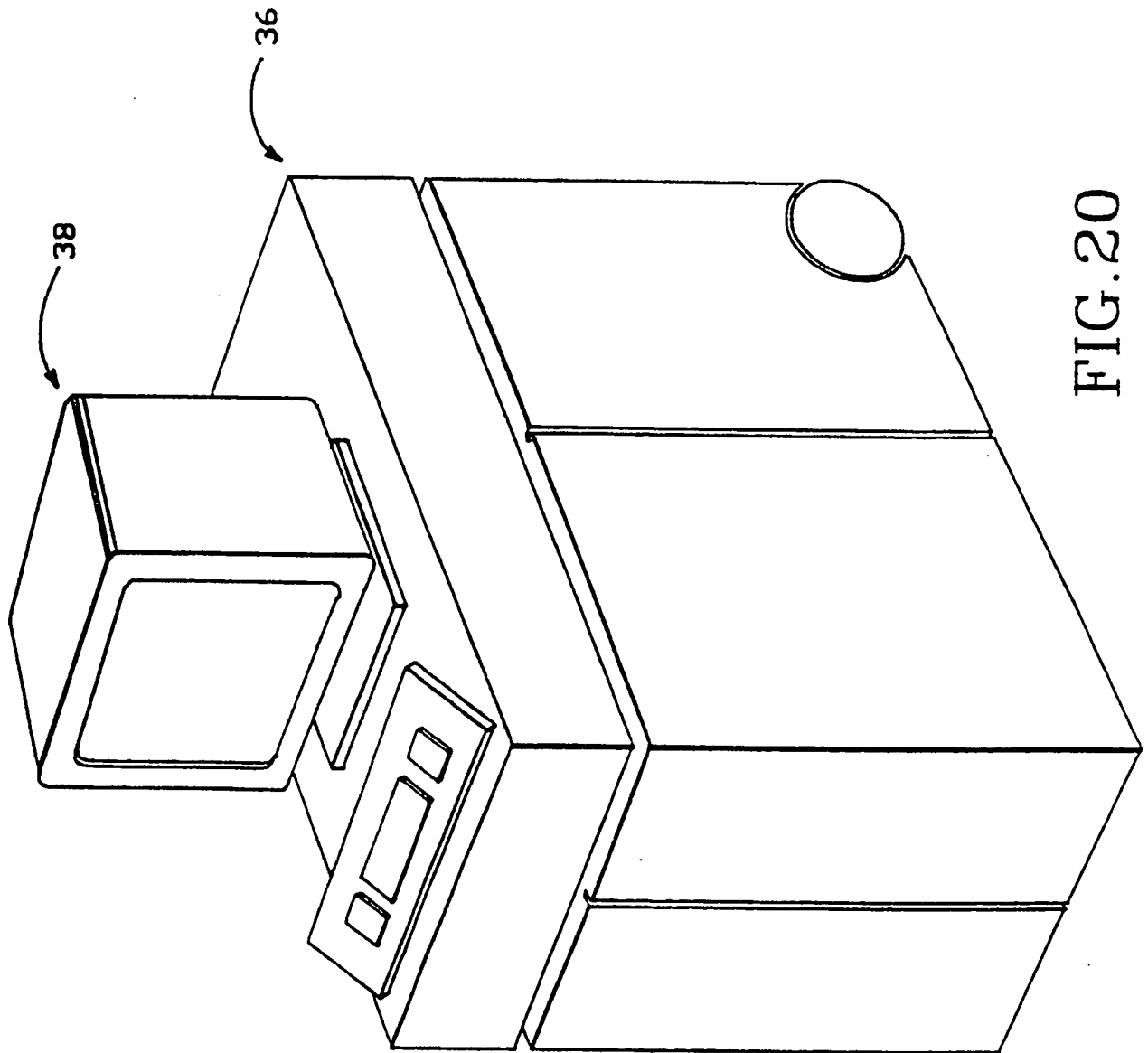


FIG. 19



21/21

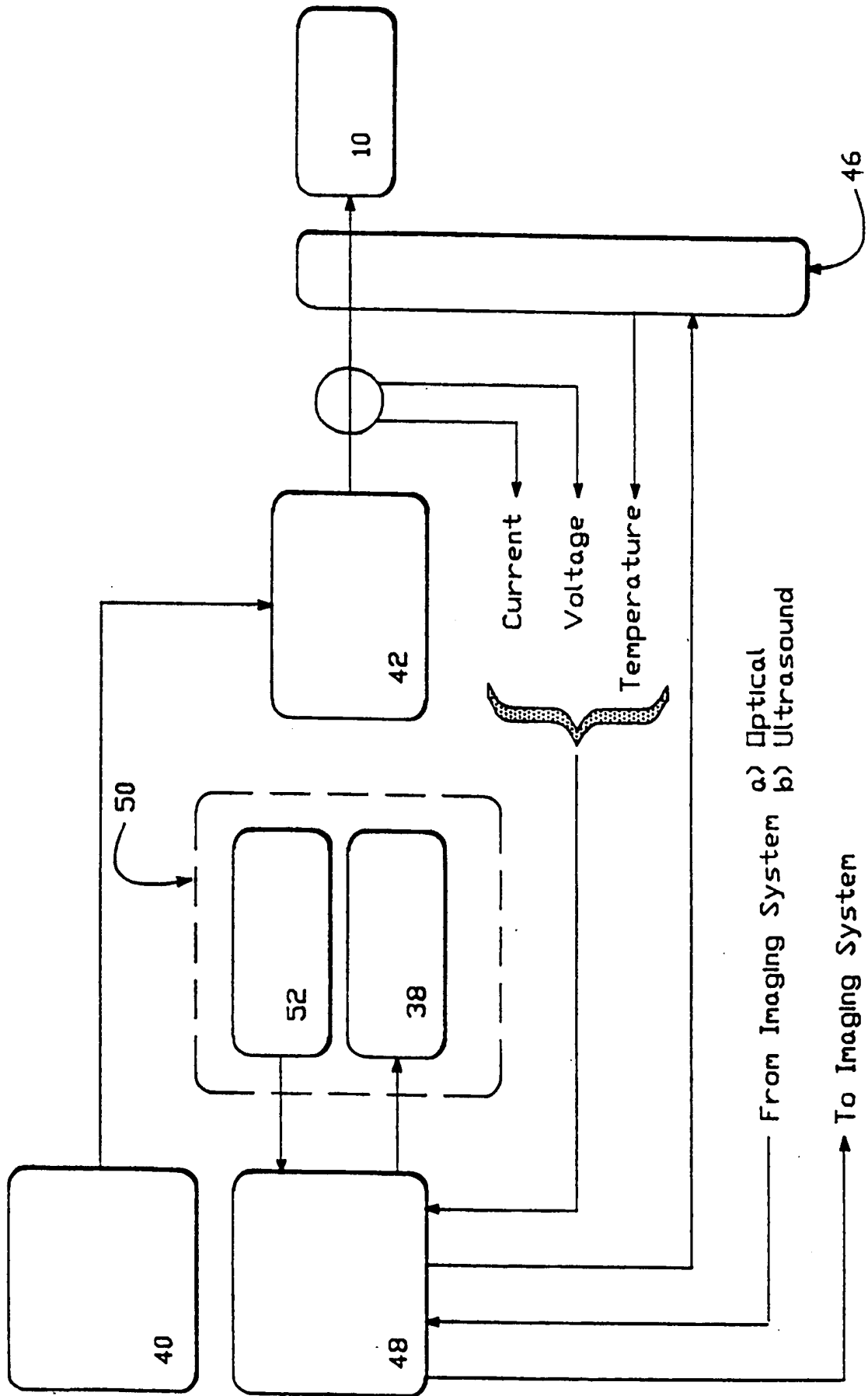


FIG. 21

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 04860 A (ZOMED INTERNATIONAL) 22 February 1996 see the whole document -----	1-25

☐

Further documents are listed in the continuation of box C.

☒

Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

14 April 1998

Date of mailing of the international search report

21/04/1998

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Papone, F

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9604860 A	22-02-96	US 5536267 A	16-07-96
		EP 0777445 A	11-06-97
		US 5683384 A	04-11-97
-----			